

Attachment 2

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Volume II

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2/8/2021

AVERHEALTH LAB- SITE VISIT REPORT

Prepared for the State of Michigan DHHS

Prepared by:
Jarrad R. Wagner, Ph.D., F-ABFT
Wagner Toxicology Associates

Larry Broussard, Ph.D., D-ABCC

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DRAFT

Laboratory Audit Report

1. Executive Summary

Dr. Larry Broussard and Dr. Jarrad Wagner conducted a laboratory site visit from January 19-20, 2021 at Averhealth Lab in St. Louis, Missouri. In general, the site visit was performed to confirm that the laboratory personnel were performing their laboratory work in accordance with their laboratory manual or standard operating procedure (SOP), and that the laboratory manual accurately reflects what is being done in the lab. The site visitors in this case also assessed if those practices were consistent with acceptable forensic laboratory practices. The laboratory director is Dr. Michele Glinn and she supervises a staff of appropriately educated and trained laboratory staff. A relatively small number of reports was audited during the visit, and the reporting process was observed. While some issues were identified and recommendations for improvements were made, the results reported by the laboratory can be scientifically supported and forensically defended in court. The Averhealth Lab team has indicated that they have implemented improvements to provide additional confidence to the State of Michigan, Department of Health and Human Services that the results reported are accurate and defensible. The team would be willing to revisit the laboratory and assess the implementation of their recommendations or review them through a virtual site visit.

2. Site Visit

Dr. Larry Broussard and Dr. Jarrad Wagner conducted a laboratory audit January 19th and 20th, 2021 (Tuesday and Wednesday) at the Averhealth Lab located at 4709 LaGuardia, Suite 100, St. Louis, MO 63134. The laboratory director is Michelle Glinn, Ph.D., F-ABFT, and she hosted the audit team with the rest of the Averhealth Lab staff.

The site visit consisted of an inspection and data audit. Dr. Wagner conducts NLCP inspections and had also participated in CLIA and COLA accreditation audits. Dr. Broussard conducts NLCP inspections and also participates in CAP, CLIA and COLA inspections. The biographies of the site visitors are provided in [Auditor Biographies](#).

The lab is accredited by the Centers for Medicare and Medicaid Services under the Clinical Laboratory Improvement Amendments (CLIA), the State of New York, and the College of American Pathologists (CAP). It was inspected by CAP in February of 2020 and was given a glowing review: "The management team has done a great job at implementing and maintaining the CAP standards for accreditation. The SOP's have been updated since the last onsite inspection and provide sufficient detail in all areas. The lab is well maintained and has sufficient space for current operations and future growth. Bench staff are well trained and very knowledgeable in their duties."

The site visit was initiated by a tour on January 19th. The team focused on oral fluid specimens that were being processed for Michigan only. The team observed accessioning, screening, and

confirmation of oral fluid specimens. The testing process has immunoassay screening, followed by confirmation of positives with liquid chromatography-tandem mass spectrometry (LC-MS/MS). Only analytes that have screened positive are reported, according to the information in Table 1. It is common practice in forensic laboratories to only report confirmation results that area associated with positive presumptive screening tests.

Table 1. Screening and confirmation for MI DHHS

Screen Drug	Screen Cutoff	Drug Class	Confirmation Analytes	Cutoff
Amphetamines Methamphetamines	12.5 ng/mL	Amphetamines	Amphetamine	6.25 ng/mL
			MDA	6.25 ng/mL
			MDEA	6.25 ng/mL
			MDMA	6.25 ng/mL
			Methamphetamine	6.25 ng/mL
			Phentermine	6.25 ng/mL
Benzodiazepines	20 ng/mL	Benzodiazepines	Alprazolam	10 ng/mL
			Clonazepam	10 ng/mL
			Diazepam	10 ng/mL
			Flunitrazepam	10 ng/mL
			Flurazepam	10 ng/mL
			Lorazepam	10 ng/mL
			Midazolam	10 ng/mL
			Nordiazepam	10 ng/mL
			Oxazepam	10 ng/mL
			Temazepam	10 ng/mL
Buprenorphine	5 ng/mL	Buprenorphine	Buprenorphine	2.5 ng/mL
			Norbuprenorphine	2.5 ng/mL
Cocaine	3.5 ng/mL	Cocaine	Benzoylecgonine	2 ng/mL
			Cocaine	2 ng/mL
Fentanyl	2 ng/mL	Fentanyl	Fentanyl	1 ng/mL
			Norfentanyl	1 ng/mL
Opiates Oxycodone	7.5 ng/mL 10 ng/mL	Opiates	6-MAM	0.5
			Codeine	3.75 ng/mL
			Hydrocodone	3.75 ng/mL
			Hydromorphone	3.75 ng/mL
			Morphine	3.75 ng/mL
			Noroxycodone	3.75 ng/mL
			Nohydrocodone	3.75 ng/mL
			Oxycodone	5 ng/mL
			Oxymorphone	5 ng/mL
THC	1 ng/mL	THC	THC	.5 ng/mL
Tramadol	10 ng/mL	Tramadol	Tramadol	5 ng/mL

The accessioning personnel were competent and capable of assigning specimen testing without sample switches. They also performed the initial aliquot for oral fluid screening via immunoassay. All samples appear to be undergoing testing as indicated in the reporting.

If samples are negative, they are reported as such and they are stored for a short time prior to being discarded. If samples are positive in the immunoassay, the positive result is confirmed using LC-MS/MS according to Table 1, and the samples are stored for a longer duration than negative specimens in case a new analysis is requested.

We observed the preparation of a batch of confirmation samples, including standard oral fluid confirmations and some specialty analyses. We also observed a sample get aliquoted for GC/MS confirmation of ethanol. The team did not verify the GC/MS procedure or assess the method or results. This is not a common practice and it is unknown how ethanol detected in oral fluid results are related to blood alcohol concentration, but this will be followed up on in a separate report.

The personnel doing the LC-MS/MS sample preparation were competent. They used barcodes and identified the samples prior to pipetting. They used calibrated and verified pipettes, and they verified pipet performance on a weekly basis with relevant volumes.

The calibrators and quality control samples were made from separate lots and were made at the levels specified in the Standard Operating Procedure (SOP) "18- Oral Fluid Confirmation for the State of Michigan." The instruments were loaded and unloaded with care to avoid sample switches and allow for reinjection (if needed). The laboratory employs an onsite maintenance person and the LC-MS/MS units are in excellent condition. Performance is verified on a daily basis and within each batch.

The laboratory is one of approximately 100 participating labs in the College of American Pathologists (CAP) Oral Fluid Proficiency Testing program. The laboratory receives 4 sets (A-D) per year consisting of 5 samples/set. Samples are analyzed by immunoassay screening and LC-MS/MS confirmation testing and results are reported to CAP. Results of each lab are compared to the expected results and the results obtained by all of the labs. If a laboratory reports a result outside of the acceptable limits (based on the mean of the values reported by all labs), it must investigate. The results for the 4 PT sets analyzed in 2020 were reviewed during the visit to the lab, and the laboratory received acceptable scores for each set, with appropriate investigation of results outside of acceptable limits, showing that there was no evidence of any systemic problems. The laboratory performed very well on their CAP Proficiency Specimens, with a 100% accuracy score in the last proficiency test set completed in November/December of 2020.

3. Areas of Concern

Immunoassay

In reviewing the revised immunoassay cutoffs for the State of Michigan, it was discovered that the targeted concentration was calculated as the neat value and not the dilute value as intended. Also, too many opiates were included in the calibrator, as there is cross reactivity with multiple analytes in the assay used. Overall, the cutoffs for the immunoassay were more sensitive than intended since the screens were implemented. As this did not result in any false negatives, the site visit team felt this could be easily corrected. The new, correct calibrator was prepared while the team was onsite and was to be validated for implementation.

The immunoassay quality control (QC) results were reviewed on an ongoing basis to determine if they performed acceptably. While the SOP called for the numerical QC result to be quantitatively evaluated, the QC results were evaluated on a qualitative basis, such that as long as expected negatives were negative and expected positives were positive, the assay was considered to be performing acceptably. The team advised that the laboratory should establish an acceptable range of numerical results and correct the calibration if the QCs fall outside of this range, before performing analysis of MI DHHS oral fluid specimens. In the opinion of the auditors this did not create any false positives or negatives in MI DHHS specimens, as the QC results were qualitatively accurate.

Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS)

Prior to the site visit, 10 random reports and supporting data were provided to the audit team. The reports showed that some analytes were reported that were being flagged as outside identification criteria by the analytical software in use, MultiQuant. This raised a concern prior to arrival, but in and of itself wasn't necessarily an issue, since it was not known how MultiQuant was setup to flag outliers prior to the site visit.

After observation of the LC-MS/MS data processing, the team recommended that the LC-MS/MS identification criteria be clarified in the SOP. Basically, in order for an analyte to be confirmed as positive, it must fall within a specified time frame as compared to an analytical standard (retention time) and the ratio of the ion transitions that are being monitored must be within a specified tolerance to standards run in the batch. The data reviewers need to strictly follow the acceptance criteria that are included in the SOP, and it would make the review process easier if MultiQuant was setup with identical acceptance criteria to the SOP. Analytes that do not meet these requirements should not be reported. It is the understanding of the site visitors that Averhealth has now clearly defined the acceptance criteria for identification of analytes, and is using them while reporting results.

The site visitors observed that the laboratory might change the linearity model or internal standard used for a specific analyte if the quality control (QC) values were outside the normal range. While this was written into the SOP, this practice would need to be supported by method validation data to be acceptable in an analytical laboratory.

4. Conclusions

The team feels that the items of concern expressed in this report do not indicate that the laboratory has reported any false negative or false positive results. The team is confident that the observed data was forensically and scientifically defensible in a court of law. Laboratory personnel were receptive to the team's recommendations to address the concerns discussed and indicated that they would begin this process immediately. The team recommends that the laboratory provide the updated procedures for review in order to ensure that the concerns expressed have been adequately addressed and the recommendations made have been appropriately understood and implemented.

5. Auditor Biographies

Dr. Larry Broussard

Larry A. Broussard, Ph.D., DABCC, is Professor Emeritus and former Department Head, Department of Clinical Laboratory Sciences, LSU Health Sciences Center (LSUHSC) in New Orleans, Louisiana. He earned a B.S. from Louisiana State University in Baton Rouge in 1970 and a Ph.D. in chemistry from the University of Texas at Austin in 1974. In 1977, following a fellowship in the Department of Pathology at LSU Medical Center in New Orleans, he joined Medical Laboratory Associates (currently LabCorp) in Birmingham, Alabama, where he served in various positions including vice-president of technical services. He has also served as Laboratory Director of several laboratories including a SAMHSA-certified drug testing laboratory, the Toxicology Laboratory of the Orleans Parish Coroner's Office, and a regional clinical laboratory. He is board certified in clinical chemistry by the National Registry of Certified Chemists (NRCC) and the American Board of Clinical Chemistry (ABCC) and in toxicology by ABCC. Dr. Broussard received the Award for Outstanding Contributions in Education in 2004 from the American Association for Clinical Chemistry (AACC) and has received the School of Allied Health Professions Excellence in Teaching and the Allen Copping Excellence in Teaching Awards from LSUHSC in 2002 and 2005. He has more than 250 publications and presentations.

Dr. Broussard has been an active member of AACC for more than 40 years and served as President in 2008. He has served on 5 Annual Meeting Organizing Committees (AMOCs) including serving as the Chair of the 2001 AMOC. In addition to his service in AACC Dr. Broussard has served as a member of the Board of Directors of the National Academy of Clinical Biochemistry (NACB), ABCC, and NRCC and as President of NRCC. He has been selected as a fellow by NACB and the American Academy of Forensic Sciences (AAFS).

Dr. Broussard has been an inspector of SAMHSA-certified drug testing laboratories for more than 20 years and CAP-certified clinical laboratories for more than 30 years and continues to perform these inspections. He also serves as a technical specialist for Nuclear Regulatory Commission-required audits of drug-testing labs. In his capacity as Department Head he oversaw a Medical Technology Program that is certified by the National Accrediting Agency for Clinical Laboratory Sciences (NAACLS). He retired from LSUHSC in 2016. His post-retirement activities include continued activity in forensic toxicology and laboratory medicine, 9 years of service as a member of the CAP Clinical Chemistry Committee, and currently serves on the

AACC Nominations Committee. He also currently serves as Laboratory Director for 5 laboratories including 2 which perform pain management testing, 2 which perform molecular testing for respiratory pathogens, and one clinical regional reference laboratory.

Dr. Jarrad Wagner

Jarrad R. Wagner, Ph.D., F-ABFT is a Professor of Forensic Sciences at the Oklahoma State University Center for Health Sciences where he specializes in research and instruction in Forensic Toxicology and Chemistry. He is board certified as a Fellow of the American Board of Forensic Toxicology and an Associate Editor for the Journal of Analytical Toxicology. He works with tandem mass spectrometry (LC/MS/MS) and gas chromatography/mass spectrometry (GC/MS) instruments and supports forensic and clinical laboratories in method development, validation and training. He serves as a member of the AAFS/SOFT Drugs and Driving Committee, the AAFS/SOFT Oral Fluid committee, is a member of the National Safety Council Alcohol, Drugs and Impairment Division and is the Vice Chair of the Oklahoma State Board of Tests for Alcohol and Drug Influence. He is an inspector for National Laboratory Certification Program laboratories, which are Substance Abuse and Mental Health Services Administration (SAMHSA) certified.

Dr. Wagner is the laboratory director for several clinical laboratories, and supervises chemistry, as well as molecular biology laboratories. He provides expert witness in criminal and civil courts, reviewing analytical laboratory results and providing interpretation. Professor Wagner formerly served as a Chemist in the Hazardous Materials Response Unit of the FBI Laboratory, where he specialized in crime scene investigations involving hazardous materials throughout the world. Prior to the FBI, his law enforcement experience includes his time as a Forensic Scientist in the Toxicology section of the Orange County (CA) Sheriff-Coroner's office and his service as a Reserve Police Officer in the City of Irvine, CA. He is a former Assistant Professor of Chemistry and Director of the Forensic Sciences program at California State University, Fresno. Dr. Wagner earned a Ph.D. in Environmental Toxicology from the University of California at Irvine and undergraduate degrees in Biology and Chemistry.

Ex. 203

From: Parks, Colin (DHHS)
Sent: Wed, 9 Mar 2022 21:29:35 +0000
To: Machen, Shayne (DHHS)
Subject: FW: Question
Attachments: Averhealth Audit Report_Final.pdf

Shayne,

I haven't found anything else specific to probationary status or CAP (outside of CAP – College of American Pathologists being one of Averhealth's accrediting bodies). Just a quick note. Dr. Wagner (our independent assessor) was aware of and reviewed all the reports conducted on Averhealth and reviewed them. A summary of his evaluation of those reports are included in the attached.

From: Jarrad Wagner [REDACTED] MCL 15.243(1)(a)
Sent: Sunday, February 28, 2021 4:31 PM
To: Parks, Colin (DHHS) <ParksC@michigan.gov>; Mahoney, Mary Lou (DHHS) <MahoneyM2@michigan.gov>; Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Cc: Broussard, Larry <LBROUS@lsuhsc.edu>; Starling, Demetrius (DHHS) <StarlingD@michigan.gov>
Subject: Re: Question

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Colin,

Here it is what I think is the final report version. I included a section to specifically address the allegations that we were made aware of last week. Larry (cc'd) has reviewed and approved. Let me know if there are any questions.

Jarrad

From: "Parks, Colin (DHHS)" <ParksC@michigan.gov>
Date: Friday, February 26, 2021 at 8:35 AM
To: Jarrad Wagner [REDACTED] MCL 15.243(1)(a) "Mahoney, Mary Lou (DHHS)" <MahoneyM2@michigan.gov>, "Doane, Amanda (DHHS)" <DoaneA@michigan.gov>
Cc: "Broussard, Larry" <LBROUS@lsuhsc.edu>, "Starling, Demetrius (DHHS)" <StarlingD@michigan.gov>
Subject: RE: Question

Sounds perfect. Thanks Jarrad and enjoy the weekend.

From: Jarrad Wagner [REDACTED] MCL 15.243(1)(a) >
Sent: Friday, February 26, 2021 9:04 AM
To: Mahoney, Mary Lou (DHHS) <MahoneyM2@michigan.gov>; Parks, Colin (DHHS) <ParksC@michigan.gov>; Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Cc: Broussard, Larry <LBROUS@lsuhsc.edu>; Starling, Demetrius (DHHS)

<StarlingD@michigan.gov>

Subject: Re: Question

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So if you all don't mind, I will edit the original draft report we submitted to include this specific information. I will get with Larry and should be able to get this to you by Monday.

Jarrad

From: "Mahoney, Mary Lou (DHHS)" <MahoneyM2@michigan.gov>
Date: Friday, February 26, 2021 at 7:42 AM
To: "Parks, Colin (DHHS)" <ParksC@michigan.gov>, Jarrad Wagner
[REDACTED] MCL 15.243(1)(a), "Doane, Amanda (DHHS)"
<DoaneA@michigan.gov>
Cc: "Broussard, Larry" <LBROUS@lsuhsc.edu>, "Starling, Demetrius (DHHS)"
<StarlingD@michigan.gov>
Subject: RE: Question

Hi Everyone,

I did just talk with Stacie Bladen, CSA Executive Director, regarding this to clarify exactly what we would need to help address the court/MDHHS questions. I agree with Colin that a memo addressing the information you have below and specifically the questions related to the 13 errors and also the one false positive that was submitted to the court would be needed. We are meeting with a court representative on Tuesday so to have something to review would be very beneficial. Also, Stacie did ask that this information be included in your final report so that it will again be specifically identified that all concerns raised were assessed.

I too want to thank you for following up on this so quickly and greatly appreciate your assistance on this matter.

Mary Lou Mahoney
Prevention, Preservation & Protection Director
235 S. Grand Ave, Lansing MI
517-243-2743

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From: Parks, Colin (DHHS) <ParksC@michigan.gov>
Sent: Friday, February 26, 2021 8:33 AM
To: Jarrad Wagner <[REDACTED] MCL 15.243(1)(a) [REDACTED]> Doane, Amanda (DHHS)
<DoaneA@michigan.gov>
Cc: Mahoney, Mary Lou (DHHS) <MahoneyM2@michigan.gov>; Broussard, Larry
<LBROUS@lsuhsc.edu>; Parks, Colin (DHHS) <ParksC@michigan.gov>
Subject: RE: Question

I think a letter from you, perhaps even a memo that could act as an addendum to your report (your summary below is spot on!) would work great. We are very grateful for your assisting with this extra step.

Amanda, do you see that anything else needs to be addressed?

Mary Lou, do you have other thoughts?

From: Jarrad Wagner <[REDACTED] MCL 15.243(1)(a)>
Sent: Thursday, February 25, 2021 9:15 PM
To: Parks, Colin (DHHS) <ParksC@michigan.gov>; Doane, Amanda (DHHS)
<DoaneA@michigan.gov>
Cc: Mahoney, Mary Lou (DHHS) <MahoneyM2@michigan.gov>; Broussard, Larry
<LBROUS@lsuhsc.edu>
Subject: Re: Question

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Colin,

I just reviewed Dr. Riley's testimony and I did not observe the issues she references. There were an appropriate number of quality controls in the batches (>10%, 6 controls for every 50 specimens), both observed onsite in January and as described in the current SOP for Michigan Oral Fluid confirmations. If any of the controls failed in the LC-MS/MS the specimens requiring that QC were re-analyzed. I understand the issue with the 13 "false positives" now and I believe that the sequence and vial checks currently in place are sufficient to prevent a similar occurrence in the future. It was fortunate that the error was caught and the multiple checks in place are appropriate to prevent this from reoccurring. I also read through the testimony of Dominique Delagnes and found it to be accurate. Would you like this in the form of an official report, that Larry and both sign? Let me know the format you prefer. I took Jason off the email thread to avoid any appearance of conflict of interest.

Thanks,
Jarrad

From: "Parks, Colin (DHHS)" <ParksC@michigan.gov>
Date: Wednesday, February 24, 2021 at 4:08 PM
To: Jason Herzog <jherzog@averhealth.com>, "Doane, Amanda (DHHS)" <DoaneA@michigan.gov>, Jarrad Wagner <jarrad.wagner@okstate.edu>
Cc: "Mahoney, Mary Lou (DHHS)" <MahoneyM2@michigan.gov>
Subject: RE: Question

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Thanks Jason!

From: Jason Herzog <jherzog@averhealth.com>
Sent: Wednesday, February 24, 2021 5:07 PM
To: Doane, Amanda (DHHS) <DoaneA@michigan.gov>; Wagner, Jarrad <jarrad.wagner@okstate.edu>; Parks, Colin (DHHS) <ParksC@michigan.gov>
Cc: Mahoney, Mary Lou (DHHS) <MahoneyM2@michigan.gov>
Subject: Re: Question

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Dr. Wagner,
Attached for your review is an email from Judge Ackert that summarizes Ms. Riley's allegations. This email was the precursor to the memo from Judge Boyd.
Many thanks,
Jason

P.S. – sorry for the delay. I've been in the hospital with my mom and the wifi is spotty.

Jason Herzog
ceo
o 804.767.8693
m 804.955.5246
jherzog@averhealth.com | averhealth.com

From: Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Date: Wednesday, February 24, 2021 at 1:26 PM
To: Wagner, Jarrad <jarrad.wagner@okstate.edu>, Parks, Colin (DHHS) <ParksC@michigan.gov>
Cc: Mahoney, Mary Lou (DHHS) <MahoneyM2@michigan.gov>, Jason

Herzog <jherzog@averhealth.com>
Subject: RE: Question

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Jason,

Can you get whatever Dr. Wagner needs please?

Amanda

From: Wagner, Jarrad <jarrad.wagner@okstate.edu>
Sent: Wednesday, February 24, 2021 2:22 PM
To: Parks, Colin (DHHS) <ParksC@michigan.gov>
Cc: Mahoney, Mary Lou (DHHS) <MahoneyM2@michigan.gov>; Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Subject: Re: Question

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Also, I don't mind asking Averhealth for the information if you don't have it. I haven't spoken to them but I am sure they would provide whatever we need.
Jarrad

From: "Parks, Colin (DHHS)" <ParksC@michigan.gov>
Date: Wednesday, February 24, 2021 at 1:01 PM
To: Jarrad Wagner <jarrad.wagner@okstate.edu>
Cc: "Mahoney, Mary Lou (DHHS)" <MahoneyM2@michigan.gov>, "Doane, Amanda (DHHS)" <DoaneA@michigan.gov>
Subject: RE: Question

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Of course. They are referenced in the attached, which was the message the court sent out. I will ask Amanda if she has any other details.

From: Wagner, Jarrad <jarrad.wagner@okstate.edu>
Sent: Wednesday, February 24, 2021 1:49 PM
To: Parks, Colin (DHHS) <ParksC@michigan.gov>

Cc: Mahoney, Mary Lou (DHHS) <MahoneyM2@michigan.gov>
Subject: Re: Question

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Are you able to provide me with Dr. Riley's statements? That would allow me to review them and determine if they were founded or unfounded. What I have heard so far are unfounded, but we should be precise in the declaratory response.

Thanks,
Jarrad

From: "Parks, Colin (DHHS)" <ParksC@michigan.gov>
Date: Wednesday, February 24, 2021 at 12:36 PM
To: Jarrad Wagner <jarrad.wagner@okstate.edu>
Cc: "Mahoney, Mary Lou (DHHS)" <MahoneyM2@michigan.gov>
Subject: FW: Question

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Hi Jarrad,

Sorry for the above and beyond request, but had an ask for you; Is the request Judge Boyd makes below, something you would be willing to do?

You mentioned in the call with the judges that Dr. Riley's concerns were (my words) irrelevant and would not impact testing results. Is this something you would be willing to state (using your own words) in a brief memo that we could share with the judges? They seem inappropriately fixated on Dr. Riley's statements and having the air taken out of this argument would help us to resolve judicial concerns and return to Averhealth as our sole tester.

Let me know if a call would be helpful and we can discuss further.

Thanks!

From: Jason Herzog <jherzog@averhealth.com>
Sent: Wednesday, February 24, 2021 12:40 PM
To: Doane, Amanda (DHHS) <DoaneA@michigan.gov>; Parks, Colin

(DHHS) <ParksC@michigan.gov>; Melissa McKinley <mmckinley@kelley-cawthorne.com>; Carrie Linderoth <clinderoth@kelley-cawthorne.com>; Dominique Delagnes <ddelagnes@averhealth.com>
Subject: Boyd Conversation Summary

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Colin and Amanda,

Melissa and Carrie, copied on this email, had a positive conversation with Judge Boyd earlier today.

Judge Boyd would like a memo from the MDHHS Assessors that states they were [aware / made aware / not aware] of Riley's allegations and the allegations are [unfounded / require additional information to arrive at a conclusion]. I recently learned that Averhealth lab staff shared the allegations with Jarrad and Larry while they were onsite. Can you ask Jarrad and Larry to provide such a memo or note?

Additionally, Riley apparently testified for an Ingham County case in early February and the court took Riley's testimony over that of Dominique's testimony. Judge Boyd will provide the transcript for our review. We will follow-up on this as we learn more.

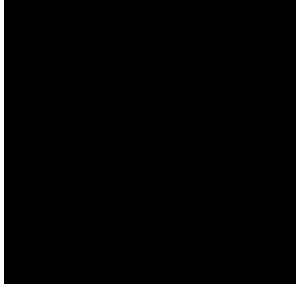
Many thanks,
Jason

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jherzog@averhealth.com | averhealth.com

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2/28/2021

Prepared by:

Jarrad R. Wagner, Ph.D., F-ABFT & Larry Broussard, Ph.D., D-ABCC

On Behalf of
Wagner Toxicology Associates

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Laboratory Audit Report

1. Executive Summary

Dr. Larry Broussard and Dr. Jarrad Wagner conducted a laboratory site visit from January 19-20, 2021 at Averhealth Lab in St. Louis, Missouri. In general, the site visit was performed to confirm that the laboratory personnel were performing their laboratory work in accordance with their laboratory manual or standard operating procedure (SOP), and that the laboratory manual accurately reflects what is being done in the lab. The site visitors in this case also assessed if those practices were consistent with acceptable forensic laboratory practices. The laboratory director is Dr. Michele Glinn and she supervises a staff of appropriately educated and trained laboratory staff. A relatively small number of reports was audited during the visit, and the reporting process was observed. Following the visit, the team was made aware of specific concerns brought to the State of Michigan, Department of Health and Human Services through the judiciary. None of the items of concern were observed during the audit or are valid in the current laboratory practices. The team specifically did not audit the software related to submission of sample data or the software used to report, but they did observe the valid analytical data used for reporting. While some issues were identified and recommendations for improvements were made, the results reported by the laboratory can be scientifically supported and forensically defended in court. The Averhealth Lab team has indicated that they have implemented improvements to provide additional confidence to the State of Michigan, Department of Health and Human Services that the results reported are accurate and defensible. The team would be willing to revisit the laboratory and assess the implementation of their recommendations or review them through a virtual site visit.

2. Site Visit

Dr. Larry Broussard and Dr. Jarrad Wagner conducted a laboratory audit January 19th and 20th, 2021 (Tuesday and Wednesday) at the Averhealth Lab located at 4709 LaGuardia, Suite 100, St. Louis, MO 63134. The laboratory director is Michelle Glinn, Ph.D., F-ABFT, and she hosted the audit team with the rest of the Averhealth Lab staff.

The site visit consisted of an inspection and data audit. Dr. Wagner conducts NLCP inspections and had also participated in CLIA and COLA accreditation audits. Dr. Broussard conducts NLCP inspections and also participates in CAP, CLIA and COLA inspections. The biographies of the site visitors are provided in [Auditor Biographies](#).

The lab is accredited by the Centers for Medicare and Medicaid Services under the Clinical Laboratory Improvement Amendments (CLIA), the State of New York, and the College of American Pathologists (CAP). It was inspected by CAP in February of 2020 and was given a glowing review: "The management team has done a great job at implementing and maintaining the CAP standards for accreditation. The SOP's have been updated since the last onsite inspection and provide sufficient detail in all areas. The lab is well maintained and has

sufficient space for current operations and future growth. Bench staff are well trained and very knowledgeable in their duties."

The site visit was initiated by a tour on January 19th. The team focused on oral fluid specimens that were being processed for Michigan only. The team observed accessioning, screening, and confirmation of oral fluid specimens. The testing process has immunoassay screening, followed by confirmation of positives with liquid chromatography-tandem mass spectrometry (LC-MS/MS). Only analytes that have screened positive are reported, according to the information in Table 1. It is common practice in forensic laboratories to only report confirmation results that are associated with positive presumptive screening tests.

Table 1. Screening and confirmation for MI DHHS

Screen Drug	Screen Cutoff	Drug Class	Confirmation Analytes	Cutoff
Amphetamines Methamphetamines	12.5 ng/mL 12.5 ng/mL	Amphetamines	Amphetamine	6.25 ng/mL
		Amphetamines	MDA	6.25 ng/mL
		Amphetamines	MDEA	6.25 ng/mL
		Amphetamines	MDMA	6.25 ng/mL
		Amphetamines	Methamphetamine	6.25 ng/mL
		Amphetamines	Phentermine	6.25 ng/mL
		Benzodiazepines	Alprazolam	10 ng/mL
Benzodiazepines	20 ng/mL	Benzodiazepines	Clonazepam	10 ng/mL
		Benzodiazepines	Diazepam	10 ng/mL
		Benzodiazepines	Flunitrazepam	10 ng/mL
		Benzodiazepines	Flurazepam	10 ng/mL
		Benzodiazepines	Lorazepam	10 ng/mL
		Benzodiazepines	Midazolam	10 ng/mL
		Benzodiazepines	Nordiazepam	10 ng/mL
		Benzodiazepines	Oxazepam	10 ng/mL
		Benzodiazepines	Temazepam	10 ng/mL
		Buprenorphine	Buprenorphine	2.5 ng/mL
Cocaine	5 ng/mL	Buprenorphine	Norbuprenorphine	2.5 ng/mL
		Cocaine	Benzoyleccgonine	2 ng/mL
Fentanyl	3.5 ng/mL	Cocaine	Cocaine	2 ng/mL
		Fentanyl	Fentanyl	1 ng/mL
		Fentanyl	Norfentanyl	1 ng/mL
Opiates Oxycodone	7.5 ng/mL 10 ng/mL	Opiates	6-MAM	0.5
		Opiates	Codeine	3.75 ng/mL
		Opiates	Hydrocodone	3.75 ng/mL
		Opiates	Hydromorphone	3.75 ng/mL
		Opiates	Morphine	3.75 ng/mL
		Opiates	Noroxycodone	3.75 ng/mL
		Opiates	Nohydrocodone	3.75 ng/mL
		Opiates	Oxycodone	5 ng/mL
		Opiates	Oxymorphone	5 ng/mL

Screen Drug	Screen Cutoff	Drug Class	Confirmation Analytes	Cutoff
THC	1 ng/mL	THC	THC	.5 ng/mL
Tramadol	10 ng/mL	Tramadol	Tramadol	5 ng/mL

The accessioning personnel were competent and capable of assigning specimen testing without sample switches. They also performed the initial aliquot for oral fluid screening via immunoassay. All samples appear to be undergoing testing as indicated in the reporting.

If samples are negative, they are reported as such and they are stored for a short time prior to being discarded. If samples are positive in the immunoassay, the positive result is confirmed using LC-MS/MS according to Table 1, and the samples are stored for a longer duration than negative specimens in case a new analysis is requested.

We observed the preparation of a batch of confirmation samples, including standard oral fluid confirmations and some specialty analyses. We also observed a sample get aliquoted for GC/MS confirmation of ethanol. The team did not verify the GC/MS procedure or assess the method or results. This is not a common practice and it is unknown how ethanol detected in oral fluid results are related to blood alcohol concentration, but this will be followed up on in a separate report.

The personnel doing the LC-MS/MS sample preparation were competent. They used barcodes and identified the samples prior to pipetting. They used calibrated and verified pipettes, and they verified pipet performance on a weekly basis with relevant volumes.

The calibrators and quality control samples were made from separate lots and were made at the levels specified in the Standard Operating Procedure (SOP) “18- Oral Fluid Confirmation for the State of Michigan.” The instruments were loaded and unloaded with care to avoid sample switches and allow for reinjection (if needed). The laboratory employs an onsite maintenance person and the LC-MS/MS units are in excellent condition. Performance is verified on a daily basis and within each batch.

The laboratory is one of approximately 100 participating labs in the College of American Pathologists (CAP) Oral Fluid Proficiency Testing program. The laboratory receives 4 sets (A-D) per year consisting of 5 samples/set. Samples are analyzed by immunoassay screening and LC-MS/MS confirmation testing and results are reported to CAP. Results of each lab are compared to the expected results and the results obtained by all of the labs. If a laboratory reports a result outside of the acceptable limits (based on the mean of the values reported by all labs), it must investigate. The results for the 4 PT sets analyzed in 2020 were reviewed during the visit to the lab, and the laboratory received acceptable scores for each set, with appropriate investigation of results outside of acceptable limits, showing that there was no evidence of any systemic problems. The laboratory performed very well on their CAP Proficiency Specimens, with a 100% accuracy score in the last proficiency test set completed in November/December of 2020.

3. Areas of Concern

Immunoassay

In reviewing the revised immunoassay cutoffs for the State of Michigan, it was discovered that the targeted concentration was calculated as the neat value and not the dilute value as intended. Also, too many opiates were included in the calibrator, as there is cross reactivity with multiple analytes in the assay used. Overall, the cutoffs for the immunoassay were more sensitive than intended since the screens were implemented. As this did not result in any false negatives, the site visit team felt this could be easily corrected. The new, correct calibrator was prepared while the team was onsite and was to be validated for implementation.

The immunoassay quality control (QC) results were reviewed on an ongoing basis to determine if they performed acceptably. While the SOP called for the numerical QC result to be quantitatively evaluated, the QC results were evaluated on a qualitative basis, such that as long as expected negatives were negative and expected positives were positive, the assay was considered to be performing acceptably. The team advised that the laboratory should establish an acceptable range of numerical results and correct the calibration if the QCs fall outside of this range, before performing analysis of MI DHHS oral fluid specimens. In the opinion of the auditors this did not create any false positives or negatives in MI DHHS specimens, as the QC results were qualitatively accurate.

Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS)

Prior to the site visit, 10 random reports and supporting data were provided to the audit team. The reports showed that some analytes were reported that were being flagged as outside identification criteria by the analytical software in use, MultiQuant. This raised a concern prior to arrival, but in and of itself wasn't necessarily an issue, since it was not known how MultiQuant was setup to flag outliers prior to the site visit.

After observation of the LC-MS/MS data processing, the team recommended that the LC-MS/MS identification criteria be clarified in the SOP. Basically, in order for an analyte to be confirmed as positive, it must fall within a specified time frame as compared to an analytical standard (retention time) and the ratio of the ion transitions that are being monitored must be within a specified tolerance to standards run in the batch. The data reviewers need to strictly follow the acceptance criteria that are included in the SOP, and it would make the review process easier if MultiQuant was setup with identical acceptance criteria to the SOP. Analytes that do not meet these requirements should not be reported. It is the understanding of the site visitors that Averhealth has now clearly defined the acceptance criteria for identification of analytes and is using them while reporting results.

The site visitors observed that the laboratory might change the linearity model or internal standard used for a specific analyte if the quality control (QC) values were outside the normal range. While this was written into the SOP, this practice would need to be supported by method validation data to be acceptable in an analytical laboratory.

4. Concerns Raised by the Judiciary

Subsequent to the visit, in the week of February 22, 2021, the team was made aware of allegations made by a former laboratory director through communication with judges and in her testimony at a trial. Specifically, the former laboratory director stated that the number of quality control (QC) specimens being run is insufficient and does not meet the 10% threshold that is required of CAP-accredited laboratories. There were an appropriate number of quality controls in the batches ($>10\%$, 6 controls for every 50 specimens), both observed onsite in January and as described in the current SOP for Michigan Oral Fluid confirmations. In fact, the laboratory is currently using those 6 independent quality control specimens for batch sizes of forty (40). The inspectors observed that if any of the controls failed in the LC-MS/MS, the specimens that required that QC were re-analyzed. The court was also concerned with a prior incident in which there were 13 “false positives” reported. Basically, in a prior batch the vials were put in the autosampler in the wrong location, causing 13 results to be associated with the wrong donors. Based on their discovery of this human error, Averhealth added independent sequence and vial checks that are currently in place, and in the opinion of the inspectors are sufficient to prevent a similar occurrence in the future. It was fortunate that the error was caught and the reports were corrected, and the multiple checks in place are appropriate to prevent this from reoccurring. The testimony of Dominique Delagnes that was provided to the inspectors was found to be accurate. There was an allegation that a false positive was reported, as a retest of the specimen was reported as negative. However, as explained in the testimony, the data in each analysis supported a positive finding with State of Michigan oral fluid cutoffs; however, the second result was reported based on an incorrect cutoff. Therefore, the data was analytically correct and reflected a positive result in both testing instances. Based on the rationale provided here, the inspectors did not observe any practices that support the allegations, and they were unsubstantiated.

5. Conclusions

The team feels that the items of concern expressed in this report do not indicate that the laboratory has reported any false negative or false positive results. The team is confident that the observed data was forensically and scientifically defensible in a court of law. Laboratory personnel were receptive to the team’s recommendations to address the concerns discussed and indicated that they would begin this process immediately. The team recommends that the laboratory provide the updated procedures for review in order to ensure that the concerns expressed have been adequately addressed and the recommendations made have been appropriately understood and implemented.

6. Auditor Biographies

Dr. Larry Broussard

Larry A. Broussard, Ph.D., DABCC, is Professor Emeritus and former Department Head, Department of Clinical Laboratory Sciences, LSU Health Sciences Center (LSUHSC) in New Orleans, Louisiana. He earned a B.S. from Louisiana State University in Baton Rouge in 1970 and a Ph.D. in chemistry from the University of Texas at Austin in 1974. In 1977, following a

fellowship in the Department of Pathology at LSU Medical Center in New Orleans, he joined Medical Laboratory Associates (currently LabCorp) in Birmingham, Alabama, where he served in various positions including vice-president of technical services. He has also served as Laboratory Director of several laboratories including a SAMHSA-certified drug testing laboratory, the Toxicology Laboratory of the Orleans Parish Coroner's Office, and a regional clinical laboratory. He is board certified in clinical chemistry by the National Registry of Certified Chemists (NRCC) and the American Board of Clinical Chemistry (ABCC) and in toxicology by ABCC. Dr. Broussard received the Award for Outstanding Contributions in Education in 2004 from the American Association for Clinical Chemistry (AACC) and has received the School of Allied Health Professions Excellence in Teaching and the Allen Copping Excellence in Teaching Awards from LSUHSC in 2002 and 2005. He has more than 250 publications and presentations.

Dr. Broussard has been an active member of AACC for more than 40 years and served as President in 2008. He has served on 5 Annual Meeting Organizing Committees (AMOCs) including serving as the Chair of the 2001 AMOC. In addition to his service in AACC Dr. Broussard has served as a member of the Board of Directors of the National Academy of Clinical Biochemistry (NACB), ABCC, and NRCC and as President of NRCC. He has been selected as a fellow by NACB and the American Academy of Forensic Sciences (AAFS).

Dr. Broussard has been an inspector of SAMHSA-certified drug testing laboratories for more than 20 years and CAP-certified clinical laboratories for more than 30 years and continues to perform these inspections. He also serves as a technical specialist for Nuclear Regulatory Commission-required audits of drug-testing labs. In his capacity as Department Head he oversaw a Medical Technology Program that is certified by the National Accrediting Agency for Clinical Laboratory Sciences (NAACLS). He retired from LSUHSC in 2016. His post-retirement activities include continued activity in forensic toxicology and laboratory medicine, 9 years of service as a member of the CAP Clinical Chemistry Committee, and currently serves on the AACC Nominations Committee. He also currently serves as Laboratory Director for 5 laboratories including 2 which perform pain management testing, 2 which perform molecular testing for respiratory pathogens, and one clinical regional reference laboratory.

Dr. Jarrad Wagner

Jarrad R. Wagner, Ph.D., F-ABFT is a Professor of Forensic Sciences at the Oklahoma State University Center for Health Sciences where he specializes in research and instruction in Forensic Toxicology and Chemistry. He is board certified as a Fellow of the American Board of Forensic Toxicology and an Associate Editor for the Journal of Analytical Toxicology. He works with tandem mass spectrometry (LC/MS/MS) and gas chromatography/mass spectrometry (GC/MS) instruments and supports forensic and clinical laboratories in method development, validation and training. He serves as a member of the AAFS/SOFT Drugs and Driving Committee, the AAFS/SOFT Oral Fluid committee, is a member of the National Safety Council Alcohol, Drugs and Impairment Division and is the Vice Chair of the Oklahoma State Board of Tests for Alcohol and Drug Influence. He is an inspector for National Laboratory Certification Program laboratories, which are Substance Abuse and Mental Health Services Administration (SAMHSA) certified.

Dr. Wagner is the laboratory director for several clinical laboratories, and supervises chemistry, toxicology and molecular biology activities. He provides expert witness in criminal and civil courts, reviewing analytical laboratory results and providing interpretation. Professor Wagner formerly served as a Chemist in the Hazardous Materials Response Unit of the FBI Laboratory, where he specialized in crime scene investigations involving hazardous materials throughout the world. Prior to the FBI, his law enforcement experience includes his time as a Forensic Scientist in the Toxicology section of the Orange County (CA) Sheriff-Coroner's office and his service as a Reserve Police Officer in the City of Irvine, CA. He is a former Assistant Professor of Chemistry and Director of the Forensic Sciences program at California State University, Fresno. Dr. Wagner earned a Ph.D. in Environmental Toxicology from the University of California at Irvine and undergraduate degrees in Biology and Chemistry.

Redaction Log

Total Number of Redactions in Document: 6

Redaction Reasons by Page

Page	Reason	Description	Occurrences
1	MCL 15.243(1)(a)	(4)(a) Information of a personal nature if public disclosure of the information would constitute a clearly unwarranted invasion of an individual's privacy	3
2	MCL 15.243(1)(a)	(4)(a) Information of a personal nature if public disclosure of the information would constitute a clearly unwarranted invasion of an individual's privacy	1
3	MCL 15.243(1)(a)	(4)(a) Information of a personal nature if public disclosure of the information would constitute a clearly unwarranted invasion of an individual's privacy	2

Redaction Log

Redaction Reasons by Exemption

Reason	Description	Pages (Count)
MCL 15.243(1)(a)	(4)(a) Information of a personal nature if public disclosure of the information would constitute a clearly unwarranted invasion of an individual's privacy	3(2) 2(1) 1(3)

Ex. 209

From: Parks, Colin (DHHS)
To: Jason Herzog; Doane, Amanda (DHHS)
Cc: Dominique Delagnes; Jacque Sheehey
Subject: RE: Urgent: Significant Development with Averhealth Drug Testing Errors
Date: Thursday, November 12, 2020 12:03:59 PM
Attachments: [image001.png](#)

Interesting.

Thanks for sharing.

From: Jason Herzog <jherzog@averhealth.com>
Sent: Thursday, November 12, 2020 12:13 PM
To: Parks, Colin (DHHS) <ParksC@michigan.gov>; Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Cc: Dominique Delagnes <ddelagnes@averhealth.com>; Jacque Sheehey <jsheehey@averhealth.com>
Subject: Fwd: Urgent: Significant Development with Averhealth Drug Testing Errors

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Colin and Amanda,
As an FYI, below is the response from Judge Ackert.
Many thanks,
Jason

Jason Herzog
ceo
o 804.767.8693
m 804.955.5246
jherzog@averhealth.com | averhealth.com

Begin forwarded message:

From: "Ackert, Terence" <terence.ackert@kentcountymi.gov>
Subject: RE: Urgent: Significant Development with Averhealth Drug Testing Errors
Date: November 12, 2020 at 11:38:44 AM EST
To: Jason Herzog <jherzog@averhealth.com>
Cc: Kelly Wagner <WagnerK@courts.mi.gov>, "Mcnabb, Deborah" <deborah.mcnabb@kentcountymi.gov>, "Feeney, Kathleen" <kathleen.feeney@kentcountymi.gov>, "Selden-Johnson, Savator (DHHS)" <Selden-JohnsonS@michigan.gov>

EXTERNAL: This email originated from outside averhealth. Do not click any links or open any attachments unless you trust the sender and know the content is safe.

Jason:

I have been in Chicago this whole week addressing a family emergency and was not able to respond to your earlier communication. I appreciate your memo regarding Dr. Sarah Riley. I will share it with the judges in Kent County.

However, I believe I should not be involved in communications with AverHealth, and the investigation of this issue must be conducted by DHHS and the State Court Administrator's Office. I will communicate with them on this issue.

Best Regards,

T. J. Ackert
Judge
Kent County Circuit Court
Family Division and Specialized Business Docket
180 Ottawa Avenue NW, Ste. 10200B
Grand Rapids, MI 49503
616-632-5091



From: Jason Herzog [<mailto:jherzog@averhealth.com>]
Sent: Thursday, November 12, 2020 10:37 AM
To: Ackert,Terence <terence.ackert@kentcountymi.gov>
Subject: Fwd: Urgent: Significant Development with Averhealth Drug Testing Errors
Importance: High

CAUTION: This email was sent from an external source. Please do not open suspicious links or attachments.

Good morning Judge Ackert,

Hope that you had a moment to thank and recognize the veterans in your life yesterday.

Attached for your consideration is a memo regarding the allegations raised by Sarah Riley.

If your schedule allows, I would appreciate a few moments of your time to discuss these events.

You are welcome to call me on my mobile at (804) 955-5246. You are also welcome to share the attached memo.

Respectfully,

Jason

Jason Herzog

ceo
o 804.767.8693
m 804.955.5246

jherzog@averhealth.com | averhealth.com

From: Ackert, Terence <terence.ackert@kentcountymi.gov>

Sent: Wednesday, November 4, 2020 4:20 PM

To: Sue Dobrich <SueD@cassco.org>; Judge Dorene S. Allen <doreneallen@co.midland.mi.us>; Kelly Wagner <wagnerk@courts.mi.gov>; Cunningham, Jacob James <cunninghamjj@oakgov.com>; Nancy Thane <nthane@tuscolacounty.org>; Smart, Richard <Richard.Smart@3rdcc.org>; Jocelyn Fabry <jfabry@saulttribe.net>; Cheryl Hill <CHILL@mqtco.org>; Langton, Lisa <langtonl@oakgov.com>; Mcnabb, Deborah <Deborah.mcnabb@kentcountymi.gov>; Feeney, Kathleen <kathleen.feeney@kentcountymi.gov>; Elizabeth Clement <ClementE@courts.mi.gov>; Megan Cavanagh <CavanaghM@courts.mi.gov>

Cc: Chang, Jooyeon (DHHS) <ChangJ4@michigan.gov>; Parks, Colin (DHHS) <ParksC@michigan.gov>; Rummel, Sandra (DHHS) <RummelS1@michigan.gov>

Subject: Urgent: Significant Development with Averhealth Drug Testing Errors

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Greetings:

I received a telephone call today from Dr. Sarah Riley, the former director of labs at Averhealth. If you will recall, Dr. Riley participated in the joint Zoom meeting with us and other representatives at Averhealth in October. Dr. Riley also participated in a call with Averhealth and members of the Parent and Children's Section of the Grand Rapids Bar Association in late October.

Dr. Riley informed me that last night she terminated her position as Lab Director with Averhealth because of her serious concerns that Averhealth has failed to follow standard testing procedures and is not compliant with the standards developed by the College of American Pathologists.

Averhealth is accredited by the College of American Pathologists and emphasized that accreditation at our meeting in October. Dr. Riley advised me that she has filed a formal complaint against Averhealth with the College of American Pathologists.

The basis of her complaint, and the concern she raised with me, is that Averhealth does not follow the standard quality control procedures when conducting a test and reporting the results to the client. Dr. Riley stated that a test should be prepared, conducted, analyzed, and then re-tested under the required protocols to confirm the results before releasing the results. Individuals at Averhealth have shortened this process to only one test and analysis because they believe Averhealth has a good test record. Dr. Riley wanted to raise these concerns at our meeting but was directed not to do so.

Dr. Riley states that in certain circumstances the failed procedures can create a false positive, especially with cocaine, in approximately 30% of the tests. The frequency of a false positive could, in some instances, increase to 50%.

I considered Dr. Riley's statements and her tone during our conversation to be credible. I was not left with the impression that she was a disgruntled employee or had some "axe to grind." Dr. Riley gave me authority to share this information.

However, without further investigation, I cannot verify her claims. Nevertheless, this information is significant and calls into question the entire DHHS testing protocol under Averhealth.

I am providing this information to each of you because you have been involved in our meetings with Averhealth. I believe this has to be investigated by DHHS, and the judges on this communication must be kept informed, and a plan for action and redress prepared.

Best Regards,

TJ

T. J. Ackert
Judge
Kent County Circuit Court

Family Division and Specialized Business Docket
180 Ottawa Avenue NW, Ste. 10200B
Grand Rapids, MI 49503
616-632-5091



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Ex. 211

From: [Doane, Amanda \(DHHS\)](#)
To: [Jason Herzog](#); [Parks, Colin \(DHHS\)](#)
Cc: [Dominique Delagnes](#); [Jacquie Sheehey](#)
Subject: RE: Talking Points
Date: Friday, November 13, 2020 6:24:00 AM

Thank you Jason. You also may want to clarify the “false positive” issue that is in truth degradation. I have had to respond to several emails over the last few days regarding false positives and explain degradation.

I will be the note taker for the meeting so I will not turn my camera or microphone on.

Amanda

From: Jason Herzog <jherzog@averhealth.com>
Sent: Friday, November 13, 2020 6:49 AM
To: Parks, Colin (DHHS) <ParksC@michigan.gov>; Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Cc: Dominique Delagnes <ddelagnes@averhealth.com>; Jacquie Sheehey <jsheehey@averhealth.com>
Subject: Talking Points

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Good morning Colin and Amanda,

While we suspect you will primarily be in listen mode during the meeting today, we wanted to provide you with the following talking points to help avoid potential confusion and ensure clarity of the message.

- For 25 years Averhealth has served as a trusted partner to courts working with over 1,800 court-related programs in more than 30 states across the country. Averhealth is committed to helping MDHHS enhance child safety, unite families, and strengthen communities with accurate test results.
- Averhealth provided Mr. Boyd with a summary to address concerns that have surfaced about the accuracy of drug test results and Averhealth is available to answer your questions.
- In the meantime, we want to reassure you that drug test results provide by Averhealth are accurate. The Averhealth laboratory is directed by two Board-certified PhDs and is one of only 30 laboratories with the College of American Pathologists-Forensic Drug Testing (CAP-FDT) certification.
- Averhealth is also accredited by the U.S. Department of Health and Human Services Clinical Laboratory Improvements Amendment (CLIA) and licensed by the Drug Enforcement Agency (DEA).
- Through a dedication to continuous improvement, Averhealth continually refines and hones processes. They fully embrace transparency – and, in fact, they encourage their team to self-report any mistakes, identify the root cause, and take action to prevent future occurrences.

- Averhealth has an outstanding reputation across the country and has earned the trust of court systems and social service agencies. You can imagine the surprise and disappointment of Averhealth when a former employee spread false allegations regarding proven test methods.
- These methods were previously inspected by outside industry experts on multiple occasions – and always received positive reports. Just to be sure, Averhealth had an independent expert review the methods over the past few days, and once again the methods received positive feedback. Averhealth has provided MDHHS the inspection history and reports.
- Averhealth uses LC-MS/MS, the top-of-the-line method. They have worked diligently over the years to create a consistent, high-quality and forensically defensible process. They are also confident that CAP-FDT will find these allegations to be unsubstantiated.
- Averhealth is taking these allegations very seriously and will defend them vigorously, including legal action, if needed. Fortunately, there is no truth to these false allegations.

Please let us know of any questions.

Many thanks,

Jason

Jason Herzog

ceo

o 804.767.8693

m 804.955.5246

jherzog@averhealth.com | averhealth.com

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Barrett, Melissa (DHHS)

From: Jarrad Wagner <jarradrwagner@gmail.com>
Sent: Thursday, January 21, 2021 7:29 AM
To: Doane, Amanda (DHHS)
Subject: Re: Averhealth Audit

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We did find a couple of issues. I am still writing the report, but I jammed the trip in this week because I was trying to get ahead of some FBI travel next week. So yes, we should probably schedule a call to discuss the findings next Friday. I will have availability the whole day, so let me know what time works for you.

Jarrad R. Wagner, Ph.D, F-ABFT
Lab Director and Professor

On Jan 21, 2021, at 6:11 AM, Doane, Amanda (DHHS) <DoaneA@michigan.gov> wrote:

OK. Did it go well? Should I try to schedule something for next week?

From: Jarrad Wagner <jarradrwagner@gmail.com>
Sent: Thursday, January 21, 2021 7:10 AM
To: Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Subject: Re: Averhealth Audit

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I am traveling today and presenting tomorrow at an online conference. I was focused on this visit and need to get ready this afternoon. I should have a report ready for you Monday that describes the site visit.

Jarrad R. Wagner, Ph.D, F-ABFT
Lab Director and Professor

On Jan 21, 2021, at 6:04 AM, Doane, Amanda (DHHS) <DoaneA@michigan.gov> wrote:

Sorry I missed your email last evening but I was already gone for the day and did not look at any email.

Does a certain time work for you today? I can send a meeting link.

Colin is available today from 9:00-9:30 or tomorrow from 9:30-10:00. All times are Eastern Standard Time

Amanda

From: Jarrad Wagner <jarradrwagner@gmail.com>
Sent: Wednesday, January 20, 2021 4:43 PM
To: Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Subject: Re: Averhealth Audit

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Amanda,

How does 4:45 pm central work for a call time? It will be about 15 minutes I think. If that doesn't work let me know and we can shift things.

Jarrad

From: "Doane, Amanda (DHHS)" <DoaneA@michigan.gov>
Date: Thursday, January 14, 2021 at 9:59 AM
To: Jarrad Wagner <jarradrwagner@gmail.com>
Subject: RE: Averhealth Audit

Here is the report I referenced. Page 29 has the cutoff levels

-----Original Appointment-----

From: [<jarradrwagner@gmail.com>](mailto:jarradrwagner@gmail.com)
Sent: Friday, January 8, 2021 11:29 AM
To: jarradrwagner@gmail.com; Bryan, Kevin (DHHS); Doane, Amanda (DHHS); Larry; Parks, Colin (DHHS)
Subject: Averhealth Audit
When: Thursday, January 14, 2021 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where:

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You have been invited to the following event.

Averhealth Audit

When Thu Jan 14, 2021 9am – 10am Central Time - Chicago

Where

Calendar doanea@michigan.gov

Who

- jarradwagner@gmail.com - organizer
- Kevin (DHHS)
- Amanda (DHHS)
- Larry
- Parks

[more details »](#)

Jarrad Wagner is inviting you to a scheduled Zoom meeting.

Topic: Averhealth Audit

Time: Jan 14, 2021 09:00 AM Central Time (US and Canada)

Join Zoom Meeting

Meeting ID: [REDACTED]

Passcode: [REDACTED]

One tap mobile

[REDACTED]

[REDACTED]

Dial by your location

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Meeting ID: [REDACTED]

Find your local number:

[REDACTED]

Going (doanea@michigan.gov)? [Yes](#) - [Maybe](#) - [No](#) [more options »](#)

Invitation from [Google Calendar](#)

You are receiving this courtesy email at the account doanea@michigan.gov because you are an attendee of this event.

To stop receiving future updates for this event, decline this event. Alternatively you can sign up for a Google account at <https://calendar.google.com/calendar/> and control your notification settings for your entire calendar.

Forwarding this invitation could allow any recipient to send a response to the organizer and be added to the guest list, or regardless of their own invitation status, or to modify your RSVP. [Learn More](#)

To: Doane, Amanda (DHHS) [mailto:Amanda.Doane@hhs.gov](#)
Subject: RE: Communication
Date: February 16, 2021 at 11:52 AM
Parks, Colin (DHHS) [mailto:Colin.Parks@hhs.gov](#), Wagner, Jarrad [mailto:Jarrad.Wagner@hhs.gov](#), Jarrad Wagner [mailto:jarrad.wagner@outlook.com](#)



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Colin,

The following is what I found...

- Prior to the site visit, the assessors reviewed reports of some drug analytes being incorrectly identified as positive, even though they fell outside of the standards of practice. This does not make sense in this context. Was it detrimental to the results? Were there false positives? I do not believe so.

From: Parks, Colin (DHHS) <ParksC@michigan.gov>
Subject: RE: Communication
Date: February 23, 2021 at 10:09 AM
To: Jarrad Wagner <jarradrwagner@gmail.com>, Doane, Amanda (DHHS) <DoaneA@michigan.gov>



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Thanks Jarrad.

From: Jarrad Wagner <jarradrwagner@gmail.com>
Sent: Tuesday, February 23, 2021 9:40 AM
To: Parks, Colin (DHHS) <ParksC@michigan.gov>; Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Subject: Re: Communication

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Colin,
I should have this back to you later today.
Thanks,
Jarrad

From: "Parks, Colin (DHHS)" <ParksC@michigan.gov>
Date: Tuesday, February 16, 2021 at 3:42 PM
To: Jarrad Wagner <jarradrwagner@gmail.com>, "Doane, Amanda (DHHS)" <DoaneA@michigan.gov>
Subject: RE: Communication

Thanks Jarrad and my apologies for the mix-up. I have modified the statement in the attached- please use this version for review.

I spoke with Judge Boyd today (he issued a memo from our State Court

Administrative Office, which led to the evaluation of Averhealth. They will be providing a couple of questions that I will share with you in a subsequent email.

Thanks!

From: Jarrad Wagner <jarradwagner@gmail.com>
Subject: Re: Communication
Date: February 23, 2021 at 4:55 PM
To: Parks, Colin (DHHS) <ParksC@michigan.gov>, Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Cc: Broussard, Larry <LBroussard@michigan.gov>



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Colin,
I think these edits will work. I had Larry review them also. If you need more edits let me know.
Thanks!
Jarrad

From: "Parks, Colin (DHHS)" <ParksC@michigan.gov>
Date: Tuesday, February 23, 2021 at 9:09 AM
To: Jarrad Wagner <jarradwagner@gmail.com>, "Doane, Amanda (DHHS)" <DoaneA@michigan.gov>
Subject: RE: Communication

Thanks Jarrad.

From: Jarrad Wagner <jarradwagner@gmail.com>
Sent: Tuesday, February 23, 2021 9:40 AM
To: Parks, Colin (DHHS) <ParksC@michigan.gov>; Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Subject: Re: Communication

CAUTION: This is an External email. Please send suspicious emails to abuse@michigan.gov

Colin,
I should have this back to you later today.
Thanks,
Jarrad

From: "Parks, Colin (DHHS)" <ParksC@michigan.gov>
Date: Tuesday, February 16, 2021 at 3:42 PM
To: Jarrad Wagner <jarradwagner@gmail.com>, "Doane, Amanda (DHHS)" <DoaneA@michigan.gov>
Subject: RE: Communication

Thanks Jarrad and my apologies for the mix-up. I have modified the statement in the attached- please use this version for review.



Parks, Colin (DHHS) <ParksC@michigan.gov>
RE: Communication
February 16, 2021 at 1:46 PM
To: Jarrad Wagner <jarradrwagner@gmail.com>, Doane, Amanda (DHHS) <DoaneA@michigan.gov>



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Thanks for that feedback. We will not share and I will amend.

From: Jarrad Wagner <jarradrwagner@gmail.com>
Sent: Tuesday, February 16, 2021 12:42 PM
To: Doane, Amanda (DHHS) <DoaneA@michigan.gov>; Parks, Colin (DHHS) <ParksC@michigan.gov>
Subject: Re: Communication

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Yes, that is not what I said. I said that the results were flagged as being outside of what the software settings were. It doesn't mean that these were incorrectly reported. I have lots of things to do today but I will look at this later. In the meantime, please feel free to share my report. I wouldn't share this, or what I have seen of it, since it is not correct.
Jarrad

From:



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Yes, that is not what I said. I said that the results were flagged as being outside of what the software settings were. It doesn't mean that these were incorrectly reported. I have lots of things to do today but I will look at this later. In the meantime, please feel free to share my report. I wouldn't share this, or what I have seen of it, since it is not correct.
Jarrad

From: "Doane, Amanda (DHHS)" <DoaneA@michigan.gov>
Date: Tuesday, February 16, 2021 at 10:52 AM
To: "Parks, Colin (DHHS)" <ParksC@michigan.gov>, Jarrad Wagner <jarrad.wagner@okstate.edu>, Jarrad Wagner <jarradrwagner@gmail.com>
Subject: RE: Communication

Colin,

The following is what I found...

Barrett, Melissa (DHHS)

From: Parks, Colin (DHHS)
Sent: Thursday, February 18, 2021 9:44 AM
To: Wagner, Jarrad; Jarrad Wagner
Subject: FW: Prep for Dr. Wagner Averhealth Present at CW Leadership Meeting

Good Morning Jarrad,

I wanted to make sure you had what you needed for todays meeting.

My understanding is this will not require a deep dive into the findings, but rather a review of the primary concern (resulting from the concern/complaint from the former Averhealth employee, resulting in her contact with the court-i.e., testing procedures meeting SOP and accreditation requirements) which led to the assessment, and the concerns you and Dr. Broussard noted. They will also be interested in the two concerns noted in your report and what those concerns mean in terms of how they may impact court cases. Finally, being able to provide an overall assessment of Averhealth as a testing lab. For example, how would you describe their functioning? Are there any unaddressed concerns. Sharing with them the likelihood of recommending new levels may be on their mind, but I think these other questions will take precedence.

From: Kelly Wagner <WagnerK@courts.mi.gov>
Sent: Thursday, February 18, 2021 8:57 AM
To: Parks, Colin (DHHS) <ParksC@michigan.gov>
Subject: RE: Prep for Dr. Wagner Averhealth Present at CW Leadership Meeting
Importance: High

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Hi Colin –

I didn't send the reports to the workgroup because I wasn't sure if we could/if it was final. Since the meeting is coming up, is it safe to send now or should I still hold off?

Thanks!

-Kelly

From: Parks, Colin (DHHS) <ParksC@michigan.gov>
Sent: Tuesday, February 16, 2021 11:10 AM
To: LaHaine, Ann (DHHS) <LaHaineA@michigan.gov>; Kelly Wagner <WagnerK@courts.mi.gov>; Machen, Shayne (DHHS) <MachenS@michigan.gov>; Sesti, Kelly (DHHS) <SestiK@michigan.gov>; Tom Boyd <BoydT@courts.mi.gov>
Cc: Linda Breiler <BreilerL@courts.mi.gov>; Parks, Colin (DHHS) <ParksC@michigan.gov>
Subject: RE: Prep for Dr. Wagner Averhealth Present at CW Leadership Meeting

Good morning,

Attached please find the CLIA reports, along with Dr. Wagner and Broussard's assessment of Averhealth lab functioning. We look forward to speaking with you at 1130.

-----Original Appointment-----

From: LaHaine, Ann (DHHS) <LaHaineA@michigan.gov>

Sent: Friday, February 12, 2021 2:48 PM

To: LaHaine, Ann (DHHS); Parks, Colin (DHHS); Kelly Wagner; Machen, Shayne (DHHS); Sesti, Kelly (DHHS); Tom Boyd

Cc: Linda Breiler

Subject: Prep for Dr. Wagner Averhealth Present at CW Leadership Meeting

When: Tuesday, February 16, 2021 12:30 PM-1:00 PM (UTC-05:00) Eastern Time (US & Canada).

Where: Microsoft Teams Meeting

02/12 Setting a MS Teams meeting for Tuesday, 02/16 at 12:30, thank you.

Microsoft Teams meeting

Join on your computer or mobile app



Or call in (audio only)

United States, Pontiac

Phone Conference ID:

[REDACTED]

[REDACTED]

Good afternoon,

Dr. Wagner will give a brief presentation regarding Averhealth at Thursday's CW Leadership meeting. We would like to set up a prep session if possible and are hoping you can be available at one of the times below.

02/16 12:30 -1:00, 1:00 -1:30

Barrett, Melissa (DHHS)

From: Doane, Amanda (DHHS)
Sent: Tuesday, December 15, 2020 11:33 AM
To: Jason Herzog; Luoma, Polly A. (DHHS); Laurin, Andrew (DHHS); Dominique Delagnes
Cc: Parks, Colin (DHHS); Dan Hass; Joseph Klumb; Sara Seaborg; Jane Hansen; philippsslaw@hotmail.com; Faith Sandahl; Jeffrey Rogg; mmcfee@menominee.com; Sandy Sheltrow; 'msparapani@cssup.org'; Teresa Luedeman; 'comptont@upfs.org'; 'Sara Miller (smiller@cfsup.org)'; 'sarah@upkids.com'; Sheila Nantelle; Dittrich, Cally (DHHS); Kimmell, Billie (DHHS); Mojzych, Wendy (DHHS); Malnar, Rachael (DHHS); Skytta, Justine (DHHS); Paavola, Brett (DHHS); Wagner, Samantha (DHHS); Albert, Aarika (DHHS); Burke, Alicia (DHHS); Marenger, Tammy (DHHS); Boucher, Kim (DHHS); Asplund, Sue (DHHS); Dustin and Susan Parrett; emily@upkids.com; 'Thomas Slagle'; ndeloria19@gmail.com; Michele Glinn; Doane, Amanda (DHHS); Parks, Colin (DHHS)
Subject: Averhealth meeting with Menominee Courts, MDHHS, & Attorneys

Here is the recording of today's meeting. Please let me know if there are any questions.

Amanda Doane
Department Analyst
Office of Child Welfare Policy & Procedure
Children's Services Agency
235 S. Grand Ave., Suite 510
Lansing, MI 48933
517-282-5273 work
517-241-7047 fax
DoaneA@michigan.gov



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Barrett, Melissa (DHHS)

From: MDHHS-CPU
Sent: Friday, February 19, 2021 4:47 PM
To: Doane, Amanda (DHHS); MDHHS-CPU
Cc: Parks, Colin (DHHS); Oumedian, Sarah (DHHS)
Subject: RE: Jarrad Wagner PO#02398
Attachments: Averhealth audit invoice-WTA.pdf

Hello Amanda,

You mentioned there is no December 2020 invoice. Are there October and November invoices?

Thank you,

Jacklyn Keeler | Accountant
MDHHS – Travel Services

From: Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Sent: Thursday, February 18, 2021 9:45 AM
To: MDHHS-CPU <MDHHS-CPU@michigan.gov>
Cc: Parks, Colin (DHHS) <ParksC@michigan.gov>; Oumedian, Sarah (DHHS) <OumedianS@michigan.gov>
Subject: Jarrad Wagner PO#02398
Importance: High

Please see the attached invoice that is approved to pay.

Purchase Order #	21*02397
Service Period	January 2021
Amount to Pay	\$6,995.16

There is no invoice for December 2020

Please let me know if you need anything else.

Amanda Doane
Department Analyst
Office of Child Welfare Policy & Procedure
Children's Services Agency
235 S. Grand Ave., Suite 510
Lansing, MI 48933
517-282-5273 work
517-241-7047 fax
DoaneA@michigan.gov



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Barrett, Melissa (DHHS)

From: Jarrad Wagner <jarradrwagner@gmail.com>
Sent: Friday, December 4, 2020 1:30 PM
To: Parks, Colin (DHHS)
Subject: Re: Question re; consultation
Attachments: Jarrad R. Wagner CV.pdf

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Colin,
I sent this email from my private address just to keep it separate from the university. I think we can do this assessment and give you what you need for a max of \$15k, and it will probably be less.

This includes:

- 2 Day Laboratory Site visit, 2 inspectors (Dr. Wagner and Dr. Larry Broussard), and Report of Findings
 - \$2500 each service fee, approximately \$1000 travel expenses per person
- Assessment of Specimen Type, Target Analytes and Sensitivity
 - Will be between \$5-8k, hourly at \$300/hr

I spoke with Larry and he would be available in January or February, so I think we can target 2/15 as a completion date for the project.

The contract would be with Wagner Toxicology Associates, so I will need to be setup as a Vendor. And I can invoice as needed, depending on contract structure.

Thanks,
Jarrad

From: "Parks, Colin (DHHS)" <ParksC@michigan.gov>
Date: Friday, December 4, 2020 at 10:15 AM
To: Jarrad Wagner <jarrad.wagner@okstate.edu>
Subject: RE: Question re; consultation

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Would love to meet today and am grateful for the speedy response. My afternoon is blocked-up with meetings, but would be able to meet now, or anytime in the next 90 minutes. Would that work?

From: Wagner, Jarrad <jarrad.wagner@okstate.edu>
Sent: Thursday, December 3, 2020 11:40 PM
To: Parks, Colin (DHHS) <ParksC@michigan.gov>
Subject: Re: Question re; consultation

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Hi Colin!

Yes, I am available to chat. Let me know if you can visit in the morning and I can schedule a zoom session. I currently have meetings at 10 am and 2 pm, but I can meet at 9 am central or some other time. If that is too soon we can look at next week. Thanks,

Jarrad

Jarrad R. Wagner, Ph.D, F-ABFT
Lab Director and Professor

Jarrad R. Wagner, Ph.D, F-ABFT
Lab Director and Professor

On Dec 3, 2020, at 10:31 PM, Parks, Colin (DHHS) <ParksC@michigan.gov> wrote:

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Good evening Dr. Wagner,

I was given your name by toxicologist Paul Cary. My name is Colin Parks and I am the state manager of the Children's Protective Services Program Office in Michigan. We recently consulted with Paul about some questions regarding a statewide service provider and are seeking a toxicologist to conduct an independent assessment of our statewide substance use screening provider, Averhealth/Aversys. I am reaching out to you, because we would like to ask a toxicologist to provide an independent assessment for our office to address a couple of questions regarding Averhealth's testing process, and recent errors we have encountered; In brief, we are asking for some one to provide an objective assessment of the service they provide. Is this something you would consider undertaking? Would you be willing to chat with me to discuss further? Please let me know what you think and I look forward to connecting. Thank you!

Colin Parks
Manager, CPS Program Office
Michigan Department of Health and Human Services
235 South Grand Ave.
Lansing, MI, 48933
517.388.5125

From: Jarrad Wagner <jarradrwagner@gmail.com>
Subject: Re: Purchase Order #210000002397 Assessment of MDHHS Drug Screen Levels and Current Contract
Date: January 8, 2021 at 11:11 AM
To: Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Cc: Parks, Colin (DHHS) <ParksC@michigan.gov>, Bryan, Kevin (DHHS) <BryanK@michigan.gov>, Broussard, Larry <LarryB@michigan.gov>



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Larry and I will be onsite at Averhealth January 19th and 20th. We would like to visit with you briefly next week to discuss the site visit and any particular issues that you would like examined. Please let us know if there is a time that we can have a Zoom meeting or conference call. Thanks,

Jarrad

From: "Doane, Amanda (DHHS)" <DoaneA@michigan.gov>
Date: Thursday, January 7, 2021 at 6:26 AM
To: Jarrad Wagner <jarradrwagner@gmail.com>
Cc: "Parks, Colin (DHHS)" <ParksC@michigan.gov>, "Bryan, Kevin (DHHS)" <BryanK@michigan.gov>
Subject: RE: Purchase Order #210000002397 Assessment of MDHHS Drug Screen Levels and Current Contract

Jarred,

Attached are 10 random reports of samples. They have all been redacted to remove the client name and pin number.

1. There are 9 positive and 1 negative reports
2. There are 7 from before the change in cut-off levels and 3 from after.
December 1st was the change in levels

3. There are reports from urban, suburban and rural counties
4. There are some single drug positives and some multiple drug positives
5. There is a wide variety of positive drugs (Cocaine, Methamphetamines, THC, Buprenorphine, Oxycodone, and Benzodiazepines)

Please let me know if you need anything else.

Amanda

From: Jarrad Wagner <jarradrwagner@gmail.com>
Sent: Wednesday, January 6, 2021 2:49 PM
To: Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Subject: Re: Purchase Order #210000002397 Assessment of MDHHS Drug Screen Levels and Current Contract

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&#-257;I am not retesting any samples. I am simply making sure that their laboratory documentation supports the results they sent to you. This will ensure they were not dry labbed and that there is no issue with incorrect results going on a report. Does that make sense?

Jarrad

From: "Doane, Amanda (DHHS)" <DoaneA@michigan.gov>
Date: Wednesday, January 6, 2021 at 1:46 PM
To: Jarrad Wagner <jarradrwagner@gmail.com>
Subject: RE: Purchase Order #210000002397 Assessment of MDHHS Drug Screen Levels and Current Contract

Negative results are only kept for 7 days so you will not be able to re-test any negative results.

Wagner, Jarrad <jarrad.wagner@okstate.edu>
Re: Question
February 24, 2021 at 2:17 PM
Parks, Colin (DHHS) <Colin.Parks@hhs.gov>
Mahoney, Mary Lou (DHHS) <MaryLou.Mahoney@hhs.gov>, Doane, Amanda (DHHS) <Amanda.Doane@hhs.gov>



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I need more specifics than what is provided in the attached memo. What are the 13 cases, and where is the documented correction that was sent to clients? I didn't review that at the lab because I was unaware of it. I am billing additional time to the remaining funds, as the site visit and report fees covered through the first call, but that should not be an issue. I am working with Dr. Harper on the evaluation of cutoffs/test system and can pay Larry for his time to review any additional info we receive.

Thanks,
Jarrad

From: "Parks, Colin (DHHS)" <ParksC@michigan.gov>
Date: Wednesday, February 24, 2021 at 1:01 PM
To: Jarrad Wagner <jarrad.wagner@okstate.edu>
Cc: "Mahoney, Mary Lou (DHHS)" <MahoneyM2@michigan.gov>, "Doane, Amanda (DHHS)" <DoaneA@michigan.gov>
Subject: RE: Question

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Of course. They are referenced in the attached, which was the message the court sent out. I will ask Amanda if she has any other details.

From: Wagner, Jarrad <jarrad.wagner@okstate.edu>
Sent: Wednesday, February 24, 2021 1:49 PM
To: Parks, Colin (DHHS) <ParksC@michigan.gov>
Cc: Mahoney, Mary Lou (DHHS) <MahoneyM2@michigan.gov>
Subject: Re: Question

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Are you able to provide me with Dr. Riley's statements? That would allow me to review them and determine if they were founded or unfounded. What I have heard so far are unfounded, but we should be precise in the declaratory response.
Thanks,
Jarrad

From:

From: Wagner, Jarrad <jarrad.wagner@okstate.edu>
Subject: Re: Question
Date: February 26, 2021 at 1:36 PM
To: Jason Herzog <jherzog@averhealth.com>, Doane, Amanda (DHHS) <DoaneA@michigan.gov>, Parks, Colin (DHHS) <ParksC@michigan.gov>
Cc: Mahoney, Mary Lou (DHHS) <MahoneyM2@michigan.gov>



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Jason,
I am aware of her testimony and will be addressing it in my report. Thank you!
Jarrad

From: Jason Herzog <jherzog@averhealth.com>
Date: Friday, February 26, 2021 at 9:24 AM
To: Jarrad Wagner <jarrad.wagner@okstate.edu>, "Doane, Amanda (DHHS)" <DoaneA@michigan.gov>, "Parks, Colin (DHHS)" <ParksC@michigan.gov>
Cc: "Mahoney, Mary Lou (DHHS)" <MahoneyM2@michigan.gov>
Subject: Re: Question

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Good morning Jarrad,

We were recently made aware of the attached testimony by Sarah Riley that provides additional information regarding Ms. Riley's allegations. A synthesis of Ms. Riley's testimony identifies three allegations:
i) positive results were reported despite failed quality controls (page 9, lines 18-25 and page 10 lines 1-12).

and page 10, lines 1-12;

ii) ineffective management (page 10, lines 13-20); and

iii) inappropriate direct to confirmation process (page 33, lines 21-25).

As you may recall, our Results Acceptance Criteria reads that "Positive results may not be reported unless all of the Quality Acceptance criteria are met".

Furthermore, quality control data and client samples are reviewed by two separate individuals prior to reporting specimens. No positive results were allowed to be reported if quality control failed. The Averhealth staff followed these standard operating procedures at all times. All quality control data is tracked and recorded for subsequent reference. If helpful, we can provide you additional information on this allegation and the others.

I believe that items i and iii are relevant to your review and your perspective on ii is welcome. Can you please incorporate this information into your response?

Many thanks,
Jason

Jason Herzog

ceo

o 804.767.8693

m 804.955.5246

jherzog@averhealth.com | averhealth.com

From: Wagner, Jarrad <jarrad.wagner@okstate.edu>

Date: Wednesday, February 24, 2021 at 6:47 PM

To: Jason Herzog <jherzog@averhealth.com>, Doane, Amanda (DHHS)

<DoaneA@michigan.gov>, Parks, Colin (DHHS) <ParksC@michigan.gov>

Cc: Mahoney, Mary Lou (DHHS) <MahoneyM2@michigan.gov>

Subject: Re: Question

Thank you Jason!

From: Jason Herzog <jherzog@averhealth.com>

Date: Wednesday, February 24, 2021 at 4:07 PM

To: "Doane, Amanda (DHHS)" <DoaneA@michigan.gov>, Jarrad

Wagner <jarrad.wagner@okstate.edu>, "Parks, Colin (DHHS)"

<ParksC@michigan.gov>

Cc: "Mahoney, Mary Lou (DHHS)" <MahoneyM2@michigan.gov>

Subject: Re: Question

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sender and know the content is safe

Dr. Wagner,

Attached for your review is an email from Judge Ackert that summarizes
Ms. Riley's allegations. This email was the precursor to the memo from
Judge Boyd

Many thanks,
Jason

P.S. – sorry for the delay. I've been in the hospital with my mom and the wifi is spotty.

Jason Herzog
ceo
o 804.767.8693

To: Wagner, Jarrad <jarrad.wagner@okstate.edu>
Re: Question
Date: February 26, 2021 at 1:36 PM
For Jason Herzog <jherzog@averhealth.com>, Doane, Amanda (DHHS) <DoaneA@michigan.gov>, Parks, Colin (DHHS) <ParksC@michigan.gov>, Mahoney, Mary Lou (DHHS) <MahoneyM2@michigan.gov>



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Jason,
I am aware of her testimony and will be addressing it in my report. Thank you!
Jarrad

From: Jason Herzog <jherzog@averhealth.com>
Date: Friday, February 26, 2021 at 9:24 AM
To: Jarrad Wagner <jarrad.wagner@okstate.edu>, "Doane, Amanda (DHHS)" <DoaneA@michigan.gov>, "Parks, Colin (DHHS)" <ParksC@michigan.gov>
Cc: "Mahoney, Mary Lou (DHHS)" <MahoneyM2@michigan.gov>
Subject: Re: Question

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Good morning Jarrad,

We were recently made aware of the attached testimony by Sarah Riley that provides additional information regarding Ms. Riley's allegations. A synthesis of Ms. Riley's testimony identifies three allegations:
i) positive results were reported despite failed quality controls (page 9, lines 18-25 and page 10, lines 1-12).

and page 10, lines 1-12);

ii) ineffective management (page 10, lines 13-20); and

iii) inappropriate direct to confirmation process (page 33, lines 21-25).

As you may recall, our Results Acceptance Criteria reads that "Positive results may not be reported unless all of the Quality Acceptance criteria are met".

Furthermore, quality control data and client samples are reviewed by two separate individuals prior to reporting specimens. No positive results were allowed to be reported if quality control failed. The Averhealth staff followed these standard operating procedures at all times. All quality control data is tracked and recorded for subsequent reference. If helpful, we can provide you additional information on this allegation and the others.

I believe that items i and iii are relevant to your review and your perspective on ii is welcome. Can you please incorporate this information into your response?

Many thanks,
Jason

Jason Herzog

ceo

o 804.767.8693

m 804.955.5246

jherzog@averhealth.com | averhealth.com

From: Wagner, Jarrad <jarrad.wagner@okstate.edu>

Date: Wednesday, February 24, 2021 at 6:47 PM

To: Jason Herzog <jherzog@averhealth.com>, Doane, Amanda (DHHS) <DoaneA@michigan.gov>, Parks, Colin (DHHS) <ParksC@michigan.gov>

Cc: Mahoney, Mary Lou (DHHS) <MahoneyM2@michigan.gov>

Subject: Re: Question

Thank you Jason!

From: Jason Herzog <jherzog@averhealth.com>

Date: Wednesday, February 24, 2021 at 4:07 PM

To: "Doane, Amanda (DHHS)" <DoaneA@michigan.gov>, Jarrad Wagner <jarrad.wagner@okstate.edu>, "Parks, Colin (DHHS)" <ParksC@michigan.gov>

Cc: "Mahoney, Mary Lou (DHHS)" <MahoneyM2@michigan.gov>

Subject: Re: Question

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Dr. Wagner,

Attached for your review is an email from Judge Ackert that summarizes Ms. Riley's allegations. This email was the precursor to the memo from Judge Boyd.

Many thanks,
Jason

P.S. – sorry for the delay. I've been in the hospital with my mom and the wifi is spotty.

Jason Herzog
ceo
o 804.767.8693

Doane, Amanda (DHHS)
FW: Averhealth assessment
December 17, 2020 at 6:50 AM
Jarrad Wagner

Jarrad,

I am also going to need the attached worksheet completed as best you can and some insurance documentation. Below lists the minimum insurance amounts needed. If you forward me your current insurance accord we can review it to make sure it meets the minimum requirements.

Amanda

From: Oumedian, Sarah (DHHS) <OumedianS@michigan.gov>
Sent: Wednesday, December 16, 2020 2:11 PM
To: Parks, Colin (DHHS) <ParksC@michigan.gov>; Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Cc: Goad, Sarah (DHHS) <GoadS@michigan.gov>
Subject: RE: Averhealth assessment

Colin,

I should be able to process the Purchase Order within a day or two of receiving the approved RQN. But I'm going to need two additional documents in addition to the RQN and SOW.

Amanda,

Can you help? We are also going to need a completed Vendor Question Worksheet (attached) and the Contractor will be required to provide a Certificate of Liability Insurance Certificate, as well. We reached out to Central Procurement Risk Management team and these are the recommended requirements:

Required Limits	Additional Requirements
Commercial General Liability Insurance	
<u>Minimum Limits:</u> \$1,000,000 Each Occurrence \$1,000,000 Personal & Advertising Injury \$2,000,000 Products/Completed Operations \$2,000,000 General Aggregate	Policy must be endorsed to add "the State of Michigan, its departments, divisions, agencies, offices, commissions, officers, employees, and agents" as additional insureds using endorsement CG 20 10 11 85, or both CG 20 10 12 19 and CG 20 37 12 19.
Automobile Liability Insurance	
<u>Minimum Limits:</u> \$1,000,000 Per Accident	Policy must: (1) be endorsed to add "the State of Michigan, its departments, divisions, agencies, offices, commissions, officers, employees, and agents" as additional insureds; and (2) include Hired and Non-Owned Automobile coverage.
Workers' Compensation Insurance	
<u>Minimum Limits:</u> Coverage according to applicable laws governing work activities	Waiver of subrogation, except where waiver is prohibited by law.
Employers Liability Insurance	
<u>Minimum Limits:</u> \$500,000 Each Accident \$500,000 Each Employee by Disease	

\$500,000 Aggregate Disease	
Privacy and Security Liability (Cyber Liability) Insurance	
<u>Minimum Limits:</u> \$1,000,000 Each Occurrence \$1,000,000 Annual Aggregate	Policy must cover information security and privacy liability, privacy notification costs, regulatory defense and penalties, and website media content liability.
Professional Liability (Errors and Omissions) Insurance	
<u>Minimum Limits:</u> \$3,000,000 Each Occurrence \$3,000,000 Annual Aggregate	

If any required policies provide claims-made coverage, the Contractor must: (i) provide coverage with a retroactive date before the Effective Date of the Contract or the beginning of Contract Activities; (ii) maintain coverage and provide evidence of coverage for at least three (3) years after completion of the Contract Activities; and (iii) if coverage is cancelled or not renewed, and not replaced with another claims-made policy form with a retroactive date prior to the Effective Date of this Contract, Contractor must purchase extended reporting coverage for a minimum of three (3) years after completion of work.

Contractor must: (i) provide insurance certificates to the Contract Administrator, containing the agreement or delivery order number, at Contract formation and within twenty (20) calendar days of the expiration date of the applicable policies; (ii) require that subcontractors maintain the required insurances contained in this Section; (iii) notify the Contract Administrator within five (5) business days if any policy is cancelled; and (iv) waive all rights against the State for damages covered by insurance. Failure to maintain the required insurance does not limit this waiver.

This Section is not intended to and is not to be construed in any manner as waiving, restricting or limiting the liability of either party for any obligations under this Contract (including any provisions hereof requiring Contractor to indemnify, defend and hold harmless the State).

Sorry for all of the additional items, but they are required for this type of purchase.

Thank you,
Sarah Oumedian
Department Analyst
Michigan Department of Health and Human Services
Bureau of Grants and Purchasing
235 South Grand Avenue, Suite 1201
Lansing, MI 48909
Phone: (517) 335-1969

From: Parks, Colin (DHHS) <ParksC@michigan.gov>
Sent: Wednesday, December 16, 2020 8:28 AM
To: Oumedian, Sarah (DHHS) <OumedianS@michigan.gov>; Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Cc: Goad, Sarah (DHHS) <GoadS@michigan.gov>
Subject: RE: Averhealth assessment

Thanks Amanda and Sarah.

Are there any time frames we can share with CSA leadership? They are meeting with some judges this week and any update we can provide will help our messaging on this. Thanks!

From: Oumedian, Sarah (DHHS) <OumedianS@michigan.gov>
Sent: Wednesday, December 16, 2020 8:15 AM
To: Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Cc: Parks, Colin (DHHS) <ParksC@michigan.gov>; Goad, Sarah (DHHS) <GoadS@michigan.gov>
Subject: RE: Averhealth assessment

Thank you, Amanda. This will be very helpful when I create the PO. Let me know the RQN number when it starts routing in SIGMA.

Thank you,
Sarah Oumedian
Department Analyst
Michigan Department of Health and Human Services
Bureau of Grants and Purchasing
235 South Grand Avenue, Suite 1201
Lansing, MI 48909
Phone: (517) 335-1969

From: Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Sent: Tuesday, December 15, 2020 3:55 PM
To: Oumedian, Sarah (DHHS) <OumedianS@michigan.gov>
Cc: Parks, Colin (DHHS) <ParksC@michigan.gov>; Goad, Sarah (DHHS) <GoadS@michigan.gov>
Subject: RE: Averhealth assessment
Importance: High

Sarah O.,

Attached is the first draft of the Statement of Work document. Unless you tell me different, I will attach this along with the various emails declining the work and the Wagner Toxicology Associates (Jarred Wagner) email with his price and resume.

I am trying to get Wagner Toxicology registered in SIGMA so I can do the RQN and have it complete. I will let you and budget know when that is ready for approvals in SIGMA.

Please let me know if I need to do anything else (aside from the RQN) or get you anything else.

Amanda

From: Oumedian, Sarah (DHHS) <OumedianS@michigan.gov>
Sent: Tuesday, December 8, 2020 11:51 AM
To: Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Subject: RE: Averhealth assessment

Hey! Sorry for not responding sooner. I'm in a training for the next couple of days (I'm on break now). I'll send you what I found on DTMB website and what another buyer used for their last PO.

From: Dominique Delagnes
RE: Report from Dr. Wagner and Dr. Broussard
March 11, 2021 at 10:34 AM
Doane, Amanda (DHHS)



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Good morning Amanda,

I hop you are having a good week. Anu update if this was sent to SCAO?

Thanks,

Dominique

From: Dominique Delagnes
Sent: Tuesday, March 9, 2021 5:20 PM
To: doanea@michigan.gov
Subject: Report from Dr. Wagner and Dr. Broussard

Good afternoon Amanda,

Will you please let us know when the report from Dr. Wagner and Dr. Broussard can be circulated to others.

Thank you very much.

From: Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Subject: RE: Report from Dr. Wagner and Dr. Broussard
Date: March 10, 2021 at 8:05 AM
To: Starling, Demetrius (DHHS) <StarlingD@michigan.gov>; Mahoney, Mary Lou (DHHS) <MahoneyM2@michigan.gov>
Cc: Goad, Sarah (DHHS) <GoadS@michigan.gov>



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This sounds good to me. We need to "put this to bed" so to speak. We need to ask the courts to go back to using Averhealth only as soon as possible.

Averhealth bid on a contract with the knowledge that they would be the sole provider of drug testing services for all of MDHHS cases. The price they gave us was based on that understanding and the volume expected. If we continue to allow courts to use other providers that we have to pay for, we can expect some push back from Averhealth and they perhaps have a basis to request a raise in the price of services.

I suggest that if courts are going to use an alternative provider even after we went to the time and expense of proving all allegations false by an independent assessor, then the courts are going to have to pay for any alternative provider. We do not have unlimited funds to spend on testing.

Amanda

From: Starling, Demetrius (DHHS) <StarlingD@michigan.gov>
Sent: Wednesday, March 10, 2021 7:43 AM
To: Doane, Amanda (DHHS) <DoaneA@michigan.gov>; Mahoney, Mary Lou (DHHS) <MahoneyM2@michigan.gov>
Subject: RE: Report from Dr. Wagner and Dr. Broussard

From: Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Sent: Wednesday, March 10, 2021 7:24 AM
To: Mahoney, Mary Lou (DHHS) <MahoneyM2@michigan.gov>; Starling, Demetrius (DHHS) <StarlingD@michigan.gov>

Subject: FW: Report from Dr. Wagner and Dr. Broussard

Thank you,
Sarah Oumedian
Department Analyst
Michigan Department of Health and Human Services
Bureau of Grants and Purchasing
235 South Grand Avenue, Suite 1201
Lansing, MI 48909
Phone: (517) 335-1969

From: Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Sent: Tuesday, December 8, 2020 11:48 AM
To: Oumedian, Sarah (DHHS) <OumedianS@michigan.gov>
Subject: FW: Averhealth assessment

Is there a Statement of Work template that is available so I do not have to re-invent the wheel?

From: Jarrad Wagner <jarradrwagner@gmail.com>
Sent: Tuesday, December 8, 2020 11:11 AM
To: Parks, Colin (DHHS) <ParksC@michigan.gov>
Cc: Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Subject: Re: Averhealth assessment

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Colin,

In general, a laboratory should be doing exactly what their lab manual says they are doing. We will review the lab manual to make sure the practices listed there meet forensic industry standards, and then we will observe employees while we are onsite, to ensure the employees are following appropriate procedures. This is similar to an NLCP audit, and Larry and I perform those thorough audits regularly. It will be modified slightly since this laboratory is not a SAMHSA/NLCP accredited laboratory, and this is something that we have done before. I do not have a full write-up and everything we will be looking at, but it will be in the report. If you want me to write up a full-scope it is possible, but I replied to your specific questions below.

- Validate Averhealth's testing process
 - We will audit their testing process to make sure that they are performing appropriate testing. We will observe the sample receipt process and verify that they are properly receiving specimens and documenting them. Then we will verify the analytical and reporting processes and that they are appropriate.
- Provide audit testing results (evaluating both positive and negative screen results),
 - We will ask for a list of test results in the past year or so, then select about 10 samples per month (80% positive) to review. We will identify the files we want to view so that the lab can assemble any and all

the ones we want to view so that we can assemble any and all supporting data with the reports, and we will verify that the data support the report. All specimens audited should have screening results and since some are positive we should see confirmation data. We will need to see some positives for each class being reported.

- Ensure the testing process meets CAP standards, (e.g., do Averhealth and FF have to follow CAP standards, even if they are accredited by different entities? Are they accredited by different entities?)
 - CAP is a fairly weak standard. We will identify any accreditations held by the lab and determine if the standards are being met. This may require access to audit records in possession of the laboratory.
- Identify and concerns re; staffing/testing process,
 - We will identify any concerns we have in relation to laboratory practices, including staff competency
- Assess that cut-off levels "make sense" and/or identify if levels should be adjusted (this will be an additional cost of \$5,000), How are appropriate levels determined? Based on accreditation, best practice standards, or other?
 - Your original standards were setup by a laboratory that over-estimates the value of an oral fluid result, and is not concerned enough with specificity and practical impacts of higher sensitivity (i.e. false positives). I am active on several national committees that are evaluating oral fluid cutoffs, mainly related to DUID. I am also involved in pain management testing that uses oral fluid instead of urine. Oral fluid generally contains the parent drug and not the metabolite (opposite of urine), so I will evaluate whether the analytical targets make sense. Also, I will review the goals of your testing and window of detection to help you determine if oral fluid is the appropriate specimen for your application. I am able to suggest an oral fluid screening device that could be used by your personnel onsite, as there are currently three options: Abbott Sotoxa, Draeger DT5000, and DrugWipe. This screen could be followed by a urine test that will capture a wider time frame of potential substance ingestion. The answer is best practice, but there are no specific accreditation requirements or published standards, and I believe your application is fairly unique.
- Identify cost, and time frame.
 - I thought I identified the costs- max of \$15k.
 - 2 Day Laboratory Site visit, 2 inspectors (Dr. Wagner and Dr. Larry Broussard), and Report of Findings
 - \$2500 each service fee, approximately \$1000 travel expenses per person
 - Assessment of Specimen Type, Target Analytes and Sensitivity (Dr. Wagner and Dr. Curt Harper)
 - Will be between \$5-8k, hourly at \$300/hr
 - Timeframe
 - Depending on when the contract is setup, we could be done in a month or so. Larry and I will require a week after the site visit to write the report. They will require time to prepare the data packs for our audit. So hopefully we would be onsite before February 1, then we would report back to you by February 15th.

- I may bring Dr. Curt Harper in for his oral fluid expertise when I evaluate your analyte list and sensitivity. But the contract will be with my company and I would make the arrangements.
- I think March 1st latest submission date, and could be much sooner

Thanks,
Jarrad

From: "Parks, Colin (DHHS)" <ParksC@michigan.gov>
Date: Tuesday, December 8, 2020 at 8:10 AM
To: Jarrad Wagner <jarrad.wagner@okstate.edu>
Cc: "Doane, Amanda (DHHS)" <DoaneA@michigan.gov>, "Parks, Colin (DHHS)" <ParksC@michigan.gov>
Subject: FW: Averhealth assessment

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Morning Jarrod,

We are moving toward establishing a payment process and I have copied Amanda Doane, our contract administrator as a contact person.

We have broadened the inquiry a bit and wanted to provide you with the specific questions our leadership is hoping the assessment will answer. Can you please let me know if these would be answered in your assessment and/or if any clarification is needed?

- Validate Averhealth's testing process,
- Provide audit testing results (evaluating both positive and negative screen results),
- Ensure the testing process meets CAP standards, (e.g., do Averhealth and FF have to follow CAP standards, even if they are accredited by different entities? Are they accredited by different entities?)
- Identify and concerns re; staffing/testing process,
- Assess that cut-off levels "make sense" and/or identify if levels should be adjusted (this will be an additional cost of \$5,000), How are appropriate levels determined? Based on accreditation, best practice standards, or other?
- Identify cost, and time frame.

Colin Parks
Manager, CPS Program Office
Michigan Department of Health and Human Services
235 South Grand Ave.
Lansing, MI, 48933
517.388.5125



vendor_question_work...et.docx

Ex. 215

From: Parks, Colin (DHHS)
To: Jarrad Wagner; Doane, Amanda (DHHS)
Cc: Mahoney, Mary Lou (DHHS)
Subject: RE: Question
Date: Wednesday, February 24, 2021 3:34:39 PM

Agreed. Moving backwards in my email responses (Mary Lou) and just saw this.

By the way, we just received transcripts from Dr. Riley and Ms. Delanges (Averhealth) from testimony taken in a court in Ingham County (Michigan) last week. In addition to what Jason sends, your review of that may also inform your response. I will share that in a subsequent email.

From: Jarrad Wagner <jarradrwagner@gmail.com>
Sent: Wednesday, February 24, 2021 2:43 PM
To: Doane, Amanda (DHHS) <DoaneA@michigan.gov>; Parks, Colin (DHHS) <ParksC@michigan.gov>
Cc: Mahoney, Mary Lou (DHHS) <MahoneyM2@michigan.gov>
Subject: Re: Question

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Switching back to my gmail... thanks for the memo from Averhealth's attorney. The attachments to it would be helpful, and hopefully Jason will provide them.

Based on what appears in the attorney memo, the complaints were unfounded. But it will be good to see any other documentation and verify.

I think the statement will need to be about a paragraph, describe the allegations, and then refute them.

Jarrad

From: "Doane, Amanda (DHHS)" <DoaneA@michigan.gov>
Date: Wednesday, February 24, 2021 at 1:25 PM
To: "Parks, Colin (DHHS)" <ParksC@michigan.gov>, Jarrad Wagner <jarrad.wagner@okstate.edu>
Cc: "Mahoney, Mary Lou (DHHS)" <MahoneyM2@michigan.gov>
Subject: RE: Question

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The attached is all I have.

Amanda

From: Parks, Colin (DHHS) <ParksC@michigan.gov>
Sent: Wednesday, February 24, 2021 2:01 PM
To: Wagner, Jarrad <jarrad.wagner@okstate.edu>
Cc: Mahoney, Mary Lou (DHHS) <MahoneyM2@michigan.gov>; Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Subject: RE: Question

Of course. They are referenced in the attached, which was the message the court sent out. I will ask Amanda if she has any other details.

From: Wagner, Jarrad <jarrad.wagner@okstate.edu>
Sent: Wednesday, February 24, 2021 1:49 PM
To: Parks, Colin (DHHS) <ParksC@michigan.gov>
Cc: Mahoney, Mary Lou (DHHS) <MahoneyM2@michigan.gov>
Subject: Re: Question

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Are you able to provide me with Dr. Riley's statements? That would allow me to review them and determine if they were founded or unfounded. What I have heard so far are unfounded, but we should be precise in the declaratory response.

Thanks,
Jarrad

From: "Parks, Colin (DHHS)" <ParksC@michigan.gov>
Date: Wednesday, February 24, 2021 at 12:36 PM
To: Jarrad Wagner <jarrad.wagner@okstate.edu>
Cc: "Mahoney, Mary Lou (DHHS)" <MahoneyM2@michigan.gov>
Subject: FW: Question

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Hi Jarrad,

Sorry for the above and beyond request, but had an ask for you; Is the request Judge Boyd makes below, something you would be willing to do?

You mentioned in the call with the judges that Dr. Riley's concerns were (my words) irrelevant and would not impact testing results. Is this something you would be willing to state (using your own words) in a brief memo that we could share with the judges? They seem inappropriately fixed on Dr. Riley's statements and having the air taken out of this argument would help us to resolve judicial concerns and return to Averhealth as our sole tester.

Let me know if a call would be helpful and we can discuss further.

Thanks!

From: Jason Herzog <jherzog@averhealth.com>
Sent: Wednesday, February 24, 2021 12:40 PM
To: Doane, Amanda (DHHS) <DoaneA@michigan.gov>; Parks, Colin (DHHS) <ParksC@michigan.gov>; Melissa McKinley <mmckinley@kelley-cawthorne.com>; Carrie Linderoth <clinderoth@kelley-cawthorne.com>; Dominique Delagnes <ddelagnes@averhealth.com>
Subject: Boyd Conversation Summary

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Colin and Amanda,

Melissa and Carrie, copied on this email, had a positive conversation with Judge Boyd earlier today.

Judge Boyd would like a memo from the MDHHS Assessors that states they were [aware / made aware / not aware] of Riley's allegations and the allegations are [unfounded / require additional information to arrive at a conclusion]. I recently learned that Averhealth lab staff shared the allegations with Jarrad and Larry while they were onsite. Can you ask Jarrad and Larry to provide such a memo or note?

Additionally, Riley apparently testified for an Ingham County case in early February and the court took Riley's testimony over that of Dominique's testimony. Judge Boyd will provide the transcript for our review. We will follow-up on this as we learn more.

Many thanks,
Jason

Jason Herzog
ceo

o 804.767.8693
m 804.955.5246
jherzog@averhealth.com | averhealth.com

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Ex. 217

From: Parks, Colin (DHHS)
To: Jason Herzog; Doane, Amanda (DHHS); Mahoney, Mary Lou (DHHS)
Subject: RE: Question
Date: Friday, February 26, 2021 9:33:52 AM

Thanks Jason. This provides a helpful perspective and we are grateful for the follow-up. As I step away from my prior role, I defer to Mary Lou and her team for any questions/concerns moving forward. Best of luck!

From: Jason Herzog <jherzog@averhealth.com>
Sent: Friday, February 26, 2021 10:30 AM
To: Doane, Amanda (DHHS) <DoaneA@michigan.gov>; Parks, Colin (DHHS) <ParksC@michigan.gov>; Mahoney, Mary Lou (DHHS) <MahoneyM2@michigan.gov>
Subject: Re: Question

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Amanda, Colin, and Mary Lou,

We are scheduling a discussion regarding the testimony with Judge Boyd and will update you as we learn more. We are also providing all Michigan prosecutors with the appropriate questions to ask Ms. Riley should she re-appear.

Simply asking Ms. Riley, or any other forensic toxicologists, to testify to the results specific to the case, would lead to the conclusion that the test results are accurate and forensically defensible. This relevant question was not asked. It is concerning that Ms. Riley was not asked to testify to the results specific to the case, that she was allowed to besmirch Averhealth, while Averhealth was not afforded a rebuttal, and that Ms. Riley's testimony occurred two weeks after the Averhealth testimony.

The sworn testimony provided by Ms. Riley relies on innuendo and lacks factual data. It appears that Ms. Riley failed to gain an understanding of operational procedures. Ms. Riley was retained for a fulltime onsite role, yet she worked less than halftime. In addition, Ms. Riley was learning how manage a lab that analyzes about 8,000 samples daily compared to prior experience of just 100 samples per day. Prior to gaining a full understanding of the role and without notice, Ms. Riley abruptly resigned from Averhealth and then via written correspondence threatened to sue Averhealth for over \$10,000,000 and demanded that Averhealth pay her \$1,250,000 in exchange for a release. While Ms. Riley has not yet acted on this threatened legal claim, it appears to serve as a motivating factor for her testimony.

A synthesis of Ms. Riley's testimony identifies three allegations: i) positive results were reported despite failed quality controls (page 9, lines 18-25 and page 10, lines 1-12); ii) ineffective management (page 10, lines 13-20); and iii) inappropriate direct to confirmation process (page 33, lines 21-25). The following addresses each allegation.

- 1. Positive results were reported despite failed quality controls** – Before, during, and after Ms. Riley worked with Averhealth, the results acceptance criteria read that “Positive results may not be reported unless all of the Quality Acceptance criteria are met”. Furthermore, quality control data and client samples are reviewed by two separate individuals prior to reporting specimens. In lay terms, no positive results were allowed to be reported if quality control failed. The Averhealth staff followed these standard operating procedures at all times. In fact, all quality control data is tracked and recorded for subsequent reference. A review of the quality control data, among other data, is completed prior to providing legal testimony or an affidavit. In summary, the policy explicitly prohibits reporting positive results when quality control fails and the actual data demonstrates that positive results were only reported when the quality control met acceptable standards.
- 2. Ineffective Management** – Ms. Riley alleges that she and others submitted concerns to management that were either rebuffed or ignored. First, the Averhealth management team is not aware of receiving any such concerns. Second, Averhealth management has a long track record of embracing continuous improvement and implementing recommended practices. Ms. Riley did recommend improvements, all of which were immediately approved and supported by management. The long tenure and very low turnover of Averhealth lab management indicate effective management.
- 3. Inappropriate Direct to Confirmation Process** – Three experts reviewed this common industry practice and independently concluded that it is scientifically and forensically defensible.

Please let me know of any questions.

Many thanks,
Jason

Jason Herzog
ceo
o 804.767.8693
m 804.955.5246
jherzog@averhealth.com | averhealth.com

From: Jason Herzog <jherzog@averhealth.com>
Date: Friday, February 26, 2021 at 10:23 AM
To: Wagner, Jarrad <jarrad.wagner@okstate.edu>, Doane, Amanda (DHHS) <DoaneA@michigan.gov>, Parks, Colin (DHHS) <ParksC@michigan.gov>
Cc: Mahoney, Mary Lou (DHHS) <MahoneyM2@michigan.gov>
Subject: Re: Question

Good morning Jarrad,

We were recently made aware of the attached testimony by Sarah Riley that provides additional information regarding Ms. Riley's allegations. A synthesis of Ms. Riley's testimony identifies three

allegations:

- i) positive results were reported despite failed quality controls (page 9, lines 18-25 and page 10, lines 1-12);
- ii) ineffective management (page 10, lines 13-20); and
- iii) inappropriate direct to confirmation process (page 33, lines 21-25).

As you may recall, our Results Acceptance Criteria reads that "Positive results may not be reported unless all of the Quality Acceptance criteria are met". Furthermore, quality control data and client samples are reviewed by two separate individuals prior to reporting specimens. No positive results were allowed to be reported if quality control failed. The Averhealth staff followed these standard operating procedures at all times. All quality control data is tracked and recorded for subsequent reference. If helpful, we can provide you additional information on this allegation and the others.

I believe that items i and iii are relevant to your review and your perspective on ii is welcome. Can you please incorporate this information into your response?

Many thanks,

Jason

Jason Herzog

ceo

o 804.767.8693

m 804.955.5246

jherzog@averhealth.com | averhealth.com

From: Wagner, Jarrad <jarrad.wagner@okstate.edu>

Date: Wednesday, February 24, 2021 at 6:47 PM

To: Jason Herzog <jherzog@averhealth.com>, Doane, Amanda (DHHS)

<DoaneA@michigan.gov>, Parks, Colin (DHHS) <ParksC@michigan.gov>

Cc: Mahoney, Mary Lou (DHHS) <MahoneyM2@michigan.gov>

Subject: Re: Question

Thank you Jason!

From: Jason Herzog <jherzog@averhealth.com>

Date: Wednesday, February 24, 2021 at 4:07 PM

To: "Doane, Amanda (DHHS)" <DoaneA@michigan.gov>, Jarrad Wagner

<jarrad.wagner@okstate.edu>, "Parks, Colin (DHHS)" <ParksC@michigan.gov>

Cc: "Mahoney, Mary Lou (DHHS)" <MahoneyM2@michigan.gov>

Subject: Re: Question

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safe

Dr. Wagner,

Attached for your review is an email from Judge Ackert that summarizes Ms. Riley's allegations. This email was the precursor to the memo from Judge Boyd.

Many thanks,

Jason

P.S. – sorry for the delay. I've been in the hospital with my mom and the wifi is spotty.

Jason Herzog

ceo

o 804.767.8693

m 804.955.5246

jherzog@averhealth.com | averhealth.com

From: Doane, Amanda (DHHS) <DoaneA@michigan.gov>

Date: Wednesday, February 24, 2021 at 1:26 PM

To: Wagner, Jarrad <jarrad.wagner@okstate.edu>, Parks, Colin (DHHS)
<ParksC@michigan.gov>

Cc: Mahoney, Mary Lou (DHHS) <MahoneyM2@michigan.gov>, Jason Herzog
<jherzog@averhealth.com>

Subject: RE: Question

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Jason,

Can you get whatever Dr. Wagner needs please?

Amanda

From: Wagner, Jarrad <jarrad.wagner@okstate.edu>

Sent: Wednesday, February 24, 2021 2:22 PM

To: Parks, Colin (DHHS) <ParksC@michigan.gov>

Cc: Mahoney, Mary Lou (DHHS) <MahoneyM2@michigan.gov>; Doane, Amanda (DHHS)
<DoaneA@michigan.gov>

Subject: Re: Question

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Also, I don't mind asking Averhealth for the information if you don't have it. I haven't

spoken to them but I am sure they would provide whatever we need.
Jarrad

From: "Parks, Colin (DHHS)" <ParksC@michigan.gov>
Date: Wednesday, February 24, 2021 at 1:01 PM
To: Jarrad Wagner <jarrad.wagner@okstate.edu>
Cc: "Mahoney, Mary Lou (DHHS)" <MahoneyM2@michigan.gov>, "Doane, Amanda (DHHS)" <DoaneA@michigan.gov>
Subject: RE: Question

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Of course. They are referenced in the attached, which was the message the court sent out. I will ask Amanda if she has any other details.

From: Wagner, Jarrad <jarrad.wagner@okstate.edu>
Sent: Wednesday, February 24, 2021 1:49 PM
To: Parks, Colin (DHHS) <ParksC@michigan.gov>
Cc: Mahoney, Mary Lou (DHHS) <MahoneyM2@michigan.gov>
Subject: Re: Question

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Are you able to provide me with Dr. Riley's statements? That would allow me to review them and determine if they were founded or unfounded. What I have heard so far are unfounded, but we should be precise in the declaratory response.

Thanks,
Jarrad

From: "Parks, Colin (DHHS)" <ParksC@michigan.gov>
Date: Wednesday, February 24, 2021 at 12:36 PM
To: Jarrad Wagner <jarrad.wagner@okstate.edu>
Cc: "Mahoney, Mary Lou (DHHS)" <MahoneyM2@michigan.gov>
Subject: FW: Question

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Hi Jarrad,

Sorry for the above and beyond request, but had an ask for you; Is the request Judge Boyd makes below, something you would be willing to do?

You mentioned in the call with the judges that Dr. Riley's concerns were (my words) irrelevant and would not impact testing results. Is this something you would be willing to state (using your own words) in a brief memo that we could share with the judges? They seem inappropriately fixed on Dr. Riley's statements and having the air taken out of this argument would help us to resolve judicial concerns and return to Averhealth as our sole tester.

Let me know if a call would be helpful and we can discuss further.

Thanks!

From: Jason Herzog <jherzog@averhealth.com>
Sent: Wednesday, February 24, 2021 12:40 PM
To: Doane, Amanda (DHHS) <DoaneA@michigan.gov>; Parks, Colin (DHHS) <ParksC@michigan.gov>; Melissa McKinley <mmckinley@kelley-cawthorne.com>; Carrie Linderoth <clinderoth@kelley-cawthorne.com>; Dominique Delagnes <ddelagnes@averhealth.com>
Subject: Boyd Conversation Summary

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Colin and Amanda,

Melissa and Carrie, copied on this email, had a positive conversation with Judge Boyd earlier today.

Judge Boyd would like a memo from the MDHHS Assessors that states they were [aware / made aware / not aware] of Riley's allegations and the allegations are [unfounded / require additional information to arrive at a conclusion]. I recently learned that Averhealth lab staff shared the allegations with Jarrad and Larry while they were onsite. Can you ask Jarrad and Larry to provide such a memo or note?

Additionally, Riley apparently testified for an Ingham County case in early February and the court took Riley's testimony over that of Dominique's testimony. Judge Boyd will provide the transcript for our review. We will follow-up on this as we learn more.

Many thanks,
Jason

Jason Herzog
ceo
o 804.767.8693
m 804.955.5246
jherzog@averhealth.com | averhealth.com

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Ex. 219

Subject: Averhealth introduction
Location: Microsoft Teams Meeting

Start: Mon 03/29/2021 09:00 AM
End: Mon 03/29/2021 09:00 AM
Show Time As: Tentative

Organizer: Doane, Amanda (DHHS)
Required Attendees: Starling, Demetrius (DHHS); Jason Herzog; Mahoney, Mary Lou (DHHS)
Optional Attendees: Dominique Delagnes; LaHaine, Ann (DHHS); Melissa McKinley; Carrie Linderoth

Attached are the slides for the meeting.

I am blocking Monday 3/29/21 from 10:00-11:00 as that is the next time our end is available. I am also making it a Teams meeting.

Jason & Dominique – if this date/time does not work for you just let us know and we can find another option.

Amanda

Microsoft Teams meeting

Join on your computer or mobile app

[Click here to join the meeting](#)

Or call in (audio only)

MCL 15.243(1)(u)

United States, Pontiac

Phone Conference ID: MCL 15.243(1)(u)

[Find a local number](#) | [Reset PIN](#)

[Learn More](#) | [Meeting options](#)

From: Starling, Demetrius (DHHS) <StarlingD@michigan.gov>
Sent: Monday, March 15, 2021 12:42 PM
To: Jason Herzog <jherzog@averhealth.com>; Mahoney, Mary Lou (DHHS) <MahoneyM2@michigan.gov>
Cc: Doane, Amanda (DHHS) <DoaneA@michigan.gov>; Dominique Delagnes

<ddelagnes@averhealth.com>; LaHaine, Ann (DHHS) <LaHaineA@michigan.gov>
Subject: RE: Averhealth introduction

Good afternoon Jason,

It's a pleasure to meet you, and yes I think that it would be valuable to schedule a meeting with your folks, Mary Lou, Amanda and I. Just an FYI, Mary Lou is out all this week, so we can look at something after then. In the meantime I have attached the memo and report that was shared with SCAO, which will also be shared with our department staff today as well. Please let me know if there are any questions that arise as a result of this correspondence.

Demetrius Starling (He/Him/His)
State Bureau Administrator of In Home Services
Department of Health and Human Services
810-493-0770

 Follow us on Twitter

From: Jason Herzog <jherzog@averhealth.com>
Sent: Friday, March 12, 2021 9:55 AM
To: Parks, Colin (DHHS) <ParksC@michigan.gov>; Mahoney, Mary Lou (DHHS) <MahoneyM2@michigan.gov>; Starling, Demetrius (DHHS) <StarlingD@michigan.gov>
Cc: Doane, Amanda (DHHS) <DoaneA@michigan.gov>; Dominique Delagnes <ddelagnes@averhealth.com>; Parks, Colin (DHHS) <ParksC@michigan.gov>
Subject: Re: Averhealth introduction

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Good morning Demetrius and Mary Lou,

Nice to meet via email. It would be good to schedule a review meeting, perhaps in-person if all feel safe/comfortable. In the interim, has SCAO received the report authored by Drs. Wagner and Broussard? Can we share this report? Did a memo accompany the report? If so, can you send me the memo?

Please do not hesitate to contact me with questions.

Many thanks,
Jason

Jason Herzog
ceo
o 804.767.8693

m 804.955.5246
jherzog@averhealth.com | averhealth.com

From: Parks, Colin (DHHS) <ParksC@michigan.gov>
Date: Friday, March 12, 2021 at 6:24 AM
To: Mahoney, Mary Lou (DHHS) <MahoneyM2@michigan.gov>, Starling, Demetrius (DHHS)
<StarlingD@michigan.gov>
Cc: Doane, Amanda (DHHS) <DoaneA@michigan.gov>, Jason Herzog
<jherzog@averhealth.com>, Dominique Delagnes <ddelagnes@averhealth.com>, Parks, Colin
(DHHS) <ParksC@michigan.gov>
Subject: Averhealth introduction

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Morning Demetrius and Mary Lou,

When I transitioned my work as CPS Manager, I neglected to formally introduce Jason Herzog, Averhealth's CEO. Jason and Dominique. Jason and Dominique have been essential to our contract work with Averhealth from the onset and have been very helpful during the recent assessment of their lab functioning (as well as other questions raised by our staff and the courts).

Perhaps efforts are already underway in terms of modifying recent testing processes changes (allowing other substance use testing, by other labs), but I was unsure if Averhealth had been provided guidance from MDHHS regarding how the amended assessment would lead to practice change.

I know of specific concern was the evaluation of Doctor's Broussard and Wagner on the questions raised by the judiciary following recent court hearings (the number of quality control specimens run by the lab) and finding that "the inspectors did not observe any practices that support the allegations, and they were unsubstantiated."

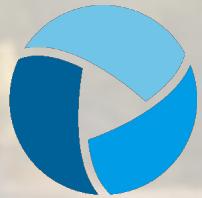
If this message is a duplicate and this is already being addressed, my apologies to all. However, I know that given all the recent changes, I missed sharing these details and for that, my apologies!

*Colin Parks
State Manager, ICPC, ICJ, RDSS
Division of Juvenile Justice
235 S. Grand Avenue
Grand Tower – Suite 1315
Lansing, MI 48933
parksc@michigan.gov
517-388-5125
517-241-9773 – fax*

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MDHHS Update
March 2021



averhealth

smarter solutions. better outcomes.





Thank you for all that you do to
enhance child safety and unite
families.

We appreciate MDHHS for
unwavering leadership and
commitment to the best
solution.



- Since 1995, Averhealth has helped to reclaim lives, unite families, and strengthen communities by helping people to overcome substance use.
- We do this by integrating technology, people and science to create and provide the smartest, most innovative solutions for substance use monitoring.
- Today, Averhealth cares for nearly 500,000 clients across 30 states serving treatment courts and social service programs.



Technology: Aversys

- Daily client notification and engagement. Clients check in daily via web, phone or text.
- Random selection.
- Aversys allows instant access to client information like testing compliance and analytics to help staffing sessions run smoothly.



People: Facing Forward

- Work side-by-side with local care team.
- Training, Support and Testimony.
- Observed Collection Specialization. Averhealth staff collect more than one million same gender observed collections annually.
- Prosocial client environment.



Science: Super Laboratory

- Nationally Certified with CLIA, CAP-FDT, and DEA Certifications.
- Broad Testing Menu. Averhealth tests for more than 1,500 substances including substances designed to avoid detection.
- Next Business Day Results.

Laboratory Accreditations



Averhealth	
Laboratory Certification(s)	CAP-FDT and CLIA
Laboratory Management Credentials	2 — PhDs 2 — Board Certified Toxicologists
Specimen Type(s)	Urine, Hair, Oral Fluid, and Sweat
Customer Footprint	Provide Services in 30 states to 2,300 customers and nearly 500,000 clients

30 US Laboratories



10,000 Laboratories



Timeline of Events



November
2020

- SCAO issues memo of concern based on allegations made by a former disgruntled employee.
- Michigan Chemistry & Toxicology Division, Infectious Disease Division, and Bureau of Labs independently concluded the Averhealth methods are scientifically appropriate.

December
2020

- U.S. Dept. of HHS conducts routine 2,000+ point inspection and extended CLIA certification of the Averhealth laboratory.
- Averhealth has a perfect CAP-FDT proficiency test, a rare industry feat.

January 2020

- Wagner Toxicology Associates completed a two-day onsite evaluation of the Averhealth laboratory concluding, "...the observed data was forensically and scientifically defensible in a court of law."
- Facts prove that the allegations have no basis.

**No other lab
has been so
thoroughly
evaluated...**

**...Affording you
trust and
confidence in
Averhealth
drug test
results**



- Courts that temporarily transitioned to alternative providers return to Averhealth.
- Continuing education for MDHHS and Court Partners – to better apply evidenced based practices and improve outcomes.
- Partnership with the Michigan Association of Treatment Court Professionals and will soon post a court training calendar.
- Providing training for Prosecutor's Association and offering the same to courts and related stakeholders.
- Supporting Lieutenant Governor's criminal justice reform efforts, transitioning from treating substance use as a crime to a health care matter.

Improvement Recommendations – Screening



The new December 2020 screening cutoff levels were set at Neat versus Dilute

- Neat levels are a quarter of dilute levels (i.e., dilute is 4x greater than neat).
- All results were valid; the cutoff was just lower than required, so more samples were sent to confirmation.
- Dilute cutoff levels were used for confirmation testing and all results were correctly reported.

Screen Quality Control samples were evaluated qualitatively, while SOP stated quantitative

- Qualitative evaluates negative versus negative and positive versus positive.
- Both Qualitative and Quantitative quality control comparisons are acceptable.
- It was suggested to use quantitative with a broader acceptance range.
- All results were correctly reported

All results were correctly reported & both recommendations were implemented within one week.

Improvement Recommendations – Confirmation



All confirmation related improvements entailed aligning SOPS with actual practices.

- Clarify select positive result certification criteria, a sample is positive when:
 - The drug peak falls within a specified time frame (retention time);
 - Compared to an analytical standard; and
 - Ratio of Ion transitions are monitored and similar.
- Configure instrument software setting to match the acceptance criteria in the SOP (instrument software parameters were stricter than SOP).
- Align method validation data with SOP regarding modification of the linearity model or internal standard.

All results were correctly reported & both recommendations were implemented within one week.

A group of people, including children and adults, are sitting on a grassy hillside. They are dressed in warm clothing, suggesting a cool day. The background shows a clear blue sky and some trees.

Thank you for all that you
do to help protect children
and unite families in
Michigan.

Redaction Log

Total Number of Redactions in Document: 2

Redaction Reasons by Page

Page	Reason	Description	Occurrences
1	MCL 15.243(1)(u)	(23) Records of a public body's security measures, including security plans, security codes and combinations, passwords, passes, keys, and security procedures, to the extent that the records relate to the ongoing security of the public body.	2

Redaction Log

Redaction Reasons by Exemption

Reason	Description	Pages (Count)
MCL 15.243(1)(u)	(23) Records of a public body's security measures, including security plans, security codes and combinations, passwords, passes, keys, and security procedures, to the extent that the records relate to the ongoing security of the public body.	1(2)

Ex. 220-A

From: [Doane, Amanda \(DHHS\)](#)
To: [Smith, Amy \(DHHS\)](#)
Subject: RE: Drug Screens
Date: Wednesday, January 20, 2021 6:19:00 AM

Our independent assessor team is in St. Louis at the Averhealth lab this week conducting the review. We expect to have the report no later than mid-February.

We also got reports from CAP-FDT and CLIA who did inspections based on the disgruntled ex-employee allegations to the accrediting bodies and to the judge and ... all accusations were deemed to be unfounded. Both accrediting bodies gave Averhealth excellent marks.

As soon as we get the report from our independent assessor we will put everything together in a communication to courts and MDHHS staff with findings.

Amanda

From: Smith, Amy (DHHS) <SmithA41@michigan.gov>
Sent: Tuesday, January 19, 2021 3:56 PM
To: Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Subject: FW: Drug Screens

Hello Amanda,
Hope you are doing well

Do you have any updates on the Averhealth issue? In regards to using alternative screening companies? Our Foster Care PM sent me this email that she received from our PA office.

Thanks

From: Knotts, Alisha (DHHS) <KnottsA@michigan.gov>
Sent: Tuesday, January 19, 2021 3:01 PM
To: Smith, Amy (DHHS) <SmithA41@michigan.gov>
Subject: FW: Drug Screens

I received this from the prosecutor's office today. Have you heard anything new related to this area with Averhealth that I could tell them.

From: Chris A. Johnson <cajohn@kalcounty.com>
Sent: Tuesday, January 19, 2021 12:51 PM
To: Knotts, Alisha (DHHS) <KnottsA@michigan.gov>
Subject: RE: Drug Screens

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Hi and happy new year! Any further information on where we are with this issue? Has everything been resolved?

Thank you,

Chris Ann Johnson

Assistant Prosecuting Attorney

Family Division-Kalamazoo Office of the Prosecuting Attorney

1536 Gull Rd, Kalamazoo, MI 49048

cajohn@kalcounty.com

269-385-6063

From: Knotts, Alisha (DHHS) <KnottsA@michigan.gov>

Sent: Tuesday, November 24, 2020 4:02 PM

To: Chris A. Johnson <cajohn@kalcounty.com>

Subject: Drug Screens

Hi Chris Ann,

We received new communication related to our substance use drug screen provider and testing. I wanted to pass on the information from the communication. I have summarized the information for you below.

MDHHS is working quickly to thoroughly review and resolve concerns raised about Averhealth and to strengthen testing reliability overall by changing testing cutoff levels effective November 30, 2020. The cutoff levels for Averhealth will be changed to meet the College of American Pathologists-Forensic Drug Testing (CAP-FDT) for all oral screen testing. CAP-FDT levels are scientifically valid, forensically defensible, and are designed to ensure the reliability of testing results. The cutoff levels will also reduce the possibility of retesting variance.

While the concerns are resolved with Averhealth, MDHHS will continue to utilize their substance use testing. At the request of the court or other parties involved in a case, MDHHS and private agency providers may seek an alternative provider to Averhealth for substance use testing. MDHHS may accommodate requests of the court without the need for an order. If alternative providers are utilized, it is important to note that the vendor and laboratories they use may result in variation of testing procedures (oral, urine and other), court testimony, costs and testing cutoff levels. We have been informed that the alternate providers must follow the established testing levels of the College of American Pathologists-Forensic Drug Testing (CAP-FDT) for all oral screens. We have an internal liaison who would identify alternative substance use providers should there be a need. Please contact me if there is a need for alternative providers and I will provide the liaison information.

Please let me know if you have any additional questions related to this change.

Alisha Knotts
Foster Care Program Manager
Kalamazoo County DHHS
269-823-4218

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Ex. 220-B

From: Parks, Colin (DHHS)
To: Doane, Amanda (DHHS)
Subject: FW: Averhealth updates
Date: Friday, January 8, 2021 11:47:15 AM
Attachments: 26D2037986 Avertest SoD_5MDR.pdf
20-144 Averhealth Ongoing Training.pdf

Do you agree and does he have this report?

From: Parks, Colin (DHHS)
Sent: Friday, January 8, 2021 12:42 PM
To: Bladen, Stacie (DHHS) <BladenS@michigan.gov>; Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Cc: Colin Parks <ParksC@michigan.gov>
Subject: FW: Averhealth updates

I have no context for this, but agree these three items should be addressed with Averhealth. This does not impact accreditation and the independent analysis will have this report to use for his assessment. Beyond ensuring Averhealth provide us a plan to address these and ensuring the independent assessor review. Is there anything else you would like us to do?

From: Bladen, Stacie (DHHS) <BladenS@michigan.gov>
Sent: Friday, January 8, 2021 12:33 PM
To: Parks, Colin (DHHS) <ParksC@michigan.gov>
Cc: Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Subject: FW: Averhealth updates

Colin the federal findings are concerning.

From: Parks, Colin (DHHS) <ParksC@michigan.gov>
Sent: Monday, January 4, 2021 5:48 PM
To: Bladen, Stacie (DHHS) <BladenS@michigan.gov>
Cc: Parks, Colin (DHHS) <ParksC@michigan.gov>; Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Subject: Averhealth updates

Hi Stacie,

Some quick Averhealth updates.

Independent Assessment of Averhealth:

- Toxicologist Jarrad Wagner has established a contractual agreement with the department to begin his independent assessment of Averhealth.
- Mr. Wagner is in contact with Dominique Delagnes (Averhealth) to obtain a list of testing reports and results. He will then:
 - Use these to randomly select some positive and negative cases.
 - Send these to the Averhealth laboratory and ask them to produce all the supporting

analytical and chain of custody information for the audit of the records.

- Mr. Wagner will also set a time for his visit to the lab.

Recent Federal inspection of Averhealth:

- Attached is the lab inspection of Averhealth, completed by the U.S. Department of Health & Human Services on December 9, 2020.
- The inspection included an evaluation of process, policy, test methods, and quality control, among other factors. There is no of the allegations put forth by Dr. Riley.
- Averhealth's accreditation has been extended.

Field training:

- There is an Averhealth staff training session Wednesday morning for new staff.
- This class is designed for new staff but anyone can attend. The Teams link is imbedded in CI 20-144 (attached).

Amanda, please jump in if I have missed anything.

Please let me know if you have any questions.

Colin Parks
Manager, CPS Program Office
Michigan Department of Health and Human Services
235 South Grand Ave.
Lansing, MI, 48933
517.388.5125

Ex. 221

From: [Doane, Amanda \(DHHS\)](#)
To: [Dominique Delagnes](#)
Cc: [Parks, Colin \(DHHS\)](#)
Subject: RE: CAP Report?
Date: Wednesday, February 10, 2021 1:51:00 PM
Attachments: [image001.png](#)

What did they do in November or December? Was that just your proficiencies that were done?

From: Dominique Delagnes <ddelagnes@averhealth.com>
Sent: Wednesday, February 10, 2021 2:39 PM
To: Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Cc: Parks, Colin (DHHS) <ParksC@michigan.gov>
Subject: RE: CAP Report?

CAUTION: This is an External email. Please send suspicious emails to abuse@michigan.gov

They have not set a date yet and we expect it to be in the next few months.

From: Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Sent: Wednesday, February 10, 2021 1:27 PM
To: Dominique Delagnes <ddelagnes@averhealth.com>
Cc: Parks, Colin (DHHS) <ParksC@michigan.gov>
Subject: RE: CAP Report?

When will they be on-site?

From: Dominique Delagnes <ddelagnes@averhealth.com>
Sent: Wednesday, February 10, 2021 1:13 PM
To: Doane, Amanda (DHHS) <DoaneA@michigan.gov>
Subject: RE: CAP Report?

CAUTION: This is an External email. Please send suspicious emails to abuse@michigan.gov

Good afternoon Amanda,

They have the information they initially requested and since our last inspection was a year ago they have opted to come on-site to conduct an inspection to conclusively resolve the matter.

Best,

Dominique

From: Doane, Amanda (DHHS) <DoaneA@michigan.gov>

Sent: Wednesday, February 10, 2021 12:22 PM

To: Dominique Delagnes <ddelagnes@averhealth.com>

Subject: CAP Report?

EXTERNAL: This email originated from outside averhealth. Do not click any links or open any attachments unless you trust the sender and know the content is safe.

Did you ever get the CAP report and submit your response to any issues? If so, can you please send me those?

Amanda Doane
Department Analyst
Office of Child Welfare Policy & Procedure
Children's Services Agency
235 S. Grand Ave., Suite 510
Lansing, MI 48933
517-282-5273 work
517-241-7047 fax
DoaneA@michigan.gov



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STATE OF MICHIGAN
IN THE CIRCUIT COURT FOR THE COUNTY OF INGHAM
FAMILY DIVISION

In re BK and MB, Minor(s).

FID No. 76442-1/2-NA

HONORABLE LISA MCCORMICK

OPINION AND ORDER

At a session of said Court held in the
City of Lansing, Ingham County, Michigan,
This 4th day of June, 2021.

PRESENT: HONORABLE LISA MCCORMICK, Circuit Court Judge

This matter comes before the Court on Respondent-Mother's motion to suppress drug screen results from Averhealth. The Court having reviewed the pleadings, heard testimony as well as argument, and being otherwise fully advised in the premises now **DENIES** Respondent-Mothers motion.

FINDINGS OF FACT

Petitioner admitted 12 Averhealth results for Respondent-Mother from a period of July 20, 2020 – January 21, 2021 during the Permanent Wardship Bench Trial.¹ During the course of the trial, Respondent-Mother questioned the accuracy of the Averhealth results.² On November 6, 2020, the Michigan State Court Administrative Office (SCAO) published a memorandum regarding concerns about the accuracy of drug test results provided by Averhealth. The

¹ Petitioner's Exhibit 2. The majority of the results were positive for Marijuana. All the results that were positive for marijuana were confirmed with the LC-MS/MS test and were over 2 ng/ml which is positive even under the increase to the cut off levels that went into effect on December 1, 2020.

² Respondent-Mother did not file a motion prior to the start of trial. The Court allowed Respondent-Mother to file its motion during the trial and argue the validity of the results.

memorandum set forth that an employee error led to 13 false positive test results in 2019. Averhealth sought to remedy the error through the adoption of new procedures that will provide greater oversight of the testing process. The memorandum went on to describe a subsequent false positive test result that was submitted in a court proceeding and allegations that Averhealth employee practices did not comply with the company's accreditation standards. When Department of Health and Human Services (DHHS) learned of the issue, they hired Wagner Toxicology Associates to conduct an independent investigation into the lab procedures and processes.

During the Permanent Wardship Bench Trial, witnesses were called to address concerns about the reliability of the Averhealth test results. The Court first heard testimony from Dominique Delagnes, Chief Operating Officer of Averhealth. Ms. Delagnes explained that the 13 false positive test results occurred because an employee skipped a slot when loading the samples into the testing apparatus causing each subsequently loaded sample to be sequentially off by one slot. The consequence of this error was that the test results for each sample after the skipped slot was associated with the wrong individual. Ms. Delagnes further testified that Averhealth addressed this issue by adding two more verification steps to the process in September or October of 2019 so that there are now three different individuals who check the sample sequence to prevent further error.

Ms. Delagnes explained how the false positive test result that was submitted in court and noted in the SCAO memo was not a false positive. Ms. Delagnes testified that they originally reported the test as negative. When asked to rerun the test several months later, the result was reported as positive. Ms. Delagnes explained the industry standard cutoff levels were higher than the custom Michigan cutoff levels and that Averhealth had performed an upgrade to their computer software, which caused the first test to apply the industry standard cutoffs instead of the Michigan cutoffs. Therefore, the test result was reported negative under the standard cutoff levels, but would

have reported positive had the lower Michigan cutoff levels been applied.³ Beginning on December 1, 2020, Michigan has begun to apply the higher industry standard cutoff limits.

Finally, Ms. Delagnes testified that a former employee, Dr. Sarah Riley alleged that Averhealth was not complying with accreditation standards. Subsequent to those allegations, an investigation occurred by the Michigan State Police and several other individuals from different entities through Michigan.⁴ Ms. Delagnes told this Court that the employee's claims were not substantiated and Averhealth's processes are valid, forensically defensible processes. DHHS also hired Wagner Toxicology Associates to conduct an independent investigation which was pending at the time of her testimony.

The Court next heard testimony from Dr. Sarah Riley, who testified as an expert in clinical lab science. Dr. Riley served as laboratory director for Averhealth from September 14, 2020 through November 3, 2020. Dr. Riley testified about her concern that Averhealth employees were not following standard operating procedures. She indicated that mass spectrometry is the "gold standard" method for testing in forensic toxicology. When using mass spectrometry, quality controls need to be included in every batch of specimens and the quality control samples should comprise ten percent of the batch. The quality control samples contain specific substances with specific intensities and are intended to ensure the accuracy of the results. Dr. Riley further testified that it was common practice at Averhealth for the analyst to continue to run the tests and report the results despite the quality control samples failing. Dr. Riley opined based on this practice and her observations that as much as 30% percent of the tests that Averhealth has done for Michigan could be false.

³ Transcript of testimony of Dominique Delagnes, pgs. 24-26.

⁴ Transcript of testimony of Dominique Delagnes, pgs. 14-15.

After Dr. Riley testified, DHHS received a report from an independent audit prepared by Dr. Jarrad Wagner and Dr. Larry Broussard on behalf of Wagner Toxicology Associates. Dr. Wagner testified as an expert in Forensic Science, Forensic Toxicology and Forensic Lab Science. Dr. Wagner indicated that his firm was hired by DHHS to conduct an audit of Averhealth. When Dr. Wagner was hired, he was not aware of the memo from SCAO dated November 6, 2020. Dr. Wagner and Dr. Broussard conducted a 2-day site visit on January 19-20, 2021. The purpose of the site visit was to confirm that personnel were conducting work in conformance with their standard operating procedure. As part of this site visit, a small number of reports were audited and he observed the laboratory process. There were some recommendations made but he opined the results reported were accurate and defensible.⁵ In addition to his site visit and report, Dr. Wagner testified that he reviewed three laboratory results submitted by the Respondent-Mother. The collection dates were September 29, 2020, December 18, 2020, December 31, 2020.⁶ It should be noted that the September 29, 2020 result was during Dr. Riley's tenure at Averhealth. He reviewed all related data from these results and confirmed the accuracy of all three results.

John Tarver from Quest Laboratories testified as an expert in Forensic Toxicology. Mr. Tarver's lab conducted two hair follicle tests submitted by Respondent-Mother. The hair specimen was collected on November 24, 2020 and February 8, 2021.⁷ Both tests results were negative. Mr. Tanner did not review any of the Averhealth data or results.

ANALYSIS

⁵ Averhealth Lab – Site Visit Report, Dated February 28, 2021. Prepared by Dr. Jarrad R. Wagner & Dr. Larry Broussard.

⁶ Petitioner's Exhibit 5. The three results admitted as Petitioner's Exhibit 5 were admitted as part of the 12 results admitted as Petitioner's Exhibit 1.

⁷ Respondent-Mother's Exhibits K and L. Respondent-Mother previously admitted the same results as Exhibit A and F.

Respondent-Mother argues there are three primary issues effecting the reliability of the Averhealth drug screens that warrant their suppression. First, in 2019, an employee error led to 13 false positive test results. Second, a subsequent drug screen from Averhealth was submitted in a court proceeding and found to be a false positive. Third, the testimony of Dr. Sarah Riley established that Averhealth was not following proper accreditation standards in their testing process. Respondent-Mother also argues the Petitioner failed to disclose the Averhealth investigation amounting to a *Brady* violation.

I. THE 2019 FALSE POSITIVE DRUG TEST RESULTS.

Whether the 2019 false positive test results create ground to suppress in the case at bar depends on whether the issues that led to the faulty results has since been rectified. The evidence before the Court shows that the batch of 13 false positives was the result of an employee error wherein the employee whom loaded the batches, inadvertently skipped a slot causing each subsequent sample loaded to be off by one slot. In September or October of 2019, two more quality control checks were added to the testing process. No subsequent issues of similar nature have been brought to the Court's attention. Dr. Wagner confirmed that the additional quality control checks were occurring when he completed his site visit. Based on the testimony and evidence received by the Court, the 2019 incident appears to be a singular event that has since been rectified through the implementation of additional quality control checks. The test results in this case were provided after the two additional quality control checks were put into place and there is nothing to indicate the 2019 incident affected any of Respondent-Mother's results.

II. THE SUBSEQUENT FALSE POSITIVE RESULT THAT WAS SUBMITTED DURING A COURT PROCEEDING.

The discovery of the subsequent false positive test has created an issue regarding the reliability of Averhealth test results. However, the evidence before the Court shows the result was

not a false positive. Instead, the evidence shows that the result reported was negative, using cutoff levels that were not standard in Michigan at the time. The Averhealth computer system caused the test to be administered under the higher industry standard cutoff levels. The subsequent retest reported positive when using Michigan cut-off levels. Thus, the issue was not the accuracy or the reliability of the results, but the cutoff levels applied to the test.

III. TESTIMONY REGARDING AVERHEALTH'S TESTING PROCESS.

Dr. Sarah Riley testified that Averhealth employees were not following standard operating procedures. Alternatively, Ms. Delagnes characterized Dr. Riley as a disgruntled employee whose claims were unsubstantiated. Dr. Riley testified how she discovered that Averhealth employees were continuing to report the results of patient samples despite the quality control samples failing. She testified that when she brought those concerns to the attention of Averhealth management, she was asked not to change anything and advised that Averhealth has contractual time constraints to report the data. Dr. Riley further testified that there were test results that she did not approve because she believed them to be inaccurate, but that she was unable to personally review every sample. When asked whether she believed the results of the tests done for the State of Michigan were erroneous, Dr. Riley indicated that she has significant concerns they were inaccurate and opined that as much as 30% of the test results could be false. However, she failed to provide any specific examples or provide the court with any examples from any results admitted in this matter.

Ms. Delagnes testified the allegations noted in the November 6, 2020 SCAO memo regarding Averhealth employees not complying with the company's accreditation standards were made by Dr. Riley who worked at Averhealth for approximately six weeks. Ms. Delagnes further testified that Averhealth employees followed standard operating procedures on a consistent basis. She informed the Court that DHHS, the Michigan State Police, and an individual named Paul

Kerry have conducted an independent investigation and concluded that Averhealth's processes are valid and forensically defensible.

Dr. Wagner provided an independent review of Averhealth's procedures. He was not aware of the allegations when he went to Averhealth for the site visit. He only learned of the allegations in between his site visit and his report being finalized. He had nothing to gain and did a thorough, complete review of the testing process. In addition to his findings, he randomly selected three results from this matter. He reviewed the data that supported the positive results and determined the results are reliable and accurate.

Mr. Tarver provided the Court with two hair follicle testing results. These results provide a 90-day look back as an indicator to determine use. Both results were negative. However, Mr. Tarver conceded that if a hair follicle test is negative, it is possible to have positive results from a different screen during the 90-day time period. This was confirmed by Eugene Schwilke, an expert in toxicology employed by Averhealth.⁸ He testified the results may be different, even if taken at the same time, depending on whether the test is oral, urine or hair. The factors include the timing of the drug exposure, the amount of use and the sensitivity as well as the methodology used.

It is the Court's duty as the trier of fact to determine the credibility of the witnesses. The Court has heard the testimony of Ms. Delagnes, Dr. Riley, Dr. Wagner and Mr. Tarver regarding the reliability of the results.⁹ Dr. Wagner conducted an independent review of Averhealth's laboratory process and testing. In addition to his independent site audit, he reviewed three results

⁸ Eugene Schwilke explained the differences between Immunonassy and confirmation tests and the different types of tests including oral, urine and hair follicle tests. He did not testify regarding the accuracy or reliability of the results.

⁹ Sarah Doane also testified. She is an employee of DHHS. She did not provide any testimony as to the validity of the Averhealth results. Eugene Schwilke did not testify as to the accuracy of the Averhealth results in this matter.

from this matter. He found the results accurate. The Court finds Dr. Wagner's testimony to be credible and reliable. Dr. Riley's testimony was speculative and did not provide the Court with any specific examples. Mr. Tarver indicated that it was possible to have a positive result 90 days before a hair follicle test. Therefore, the Court finds that the results admitted from Averhealth are reliable and denies suppression of Respondent-Mother's test results.

BRADY ALLEGATION

Respondent-Mother claims that the Petitioner failed to disclose information about investigations of Averhealth in violation of *Brady v Maryland* 373 US 83 (1963).¹⁰ The Court of Appeals in an unpublished opinion did not apply the Brady requirements in child protective proceedings. *In re Condron*, unpublished opinion per curiam of the Court of Appeals, decided August 20, 2020 (Docket No. 351240).¹¹ However, even if *Brady* did apply, the Court of Appeals adopted a four-factor Brady test. *People v Chenault*, 495 Mich 142, 151 (2014). The moving party must prove 1) that the state possessed evidence favorable to the defendant 2) that the evidence could not be obtained with any reasonable diligence 3) that the prosecution suppressed favorable evidence and 4) that the evidence if disclosed to the accused, a reasonable probability exists that would change the outcome of the proceedings. *Id.* at 151. There was no testimony that the prosecutor suppressed evidence or that the prosecutor suppressed any information specifically as to any of the results in this matter. There was also no testimony that DHHS withheld any information regarding these specific test results. Even assuming DHHS had the information about the Averhealth allegations, the evidence presented is not favorable to the

¹⁰ Respondent-Mother's Brief in Support of Motion to Suppress Averhealth Drug Test Results.

¹¹ *In re Condron* was remanded to the trial court on other grounds. After the remand and a ruling from the trial court, the case was appealed *In re Condron*, unpublished opinion per curiam of the Court of Appeals, decided January 21, 2021 (Docket No. 351240). The issue of *Brady* in child protective proceedings was not addressed in the subsequent appeal.

Respondent-Mother. The evidence shows the Averhealth results are reliable and defensible in court. Even if the Court were to apply *Brady* to this case, the court does not find a *Brady* violation.

THEREFORE, IT IS HEREBY ORDERED that Respondent Mother's motion to suppress Averhealth results is **DENIED**.

6/4/2021
DATE



HONORABLE LISA MCCORMICK